Compendium of Pharmaceuticals and Specialties

Seventeenth Edition 1982

Compendium of Pharmaceuticals and Specialties

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Compendium of Pharmaceuticals and Specialties

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Preface

The *Compendium of Pharmaceuticals and Specialties* (CPS) is a publication editorially compiled and produced by the staff of the Canadian Pharmaceutical Association for the benefit of all health professionals.

In CPS '82, the format of previous editions has been retained and the policy of making improvements has been continued. Significant improvements include an updating of the Overdose Section for many of the monographs to reflect current medical practice. Similarly, pharmacokinetic data and statements regarding use in pregnant, lactating, or geriatric patients, have been added when information is available. In many cases monographs for products containing similar active ingredients have been standardized. Monographs of significant new therapeutic agents introduced in the '82 edition include amiloride, captopril, etoposide, piroxicam, streptokinase and tranexamic acid. New products released during 1981 have been indicated by the designation "Marketed 1981". Monographs which have been either reviewed by the CPS staff or the CPS Advisory Panel have been designated "Reviewed 1982".

As an added service to the users of the CPS, those products which have been discontinued since publication of the 1981 edition are listed after the monographs of numbered specialties.

The editors express their thanks to all manufacturers and distributors who have cooperated by supplying information, offering suggestions and reading proofs. Appreciation is extended to the users of the CPS who forwarded constructive suggestions for amendments to the text and revisions in the format. Also, grateful acknowledgement is recorded for the active interest of the Canadian Medical Association, the Canadian Hospital Association, the Canadian Society of Hospital Pharmacists and the Pharmaceutical Manufacturers Association of Canada. The assistance of Jeannine Wolfe and the Ottawa Valley Regional Drug Information Services is greatly appreciated. The financial support of the following companies is gratefully acknowledged.

Abbott; Adria; Alcon; Allen & Hanburys; Alza; Anca; Astra; Ayerst; Beecham; Boehringer; Bristol; Burroughs Wellcome; Calmic; Charton; Ciba; Connaught; Cooper; Cowling & Braithwaite; Desbergers; Dormer; Dow; Endo; Ferring; Fisons; Frosst; Geigy; Glaxo; Harris; Hoechst; Hoffmann-La Roche; Horner; I.A.F.; ICI Pharma; ICN; Jamieson; Janssen; Johnson & Johnson; Kabi Vitrum; K-Line; Kremers-Urban; Lederle; Leo; Lilly; McNeil; Mead Johnson; Merck Sharp & Dohme; Merrell; Miles; Nadeau; Nordic; Norwich-Eaton; Nova; Novopharm; Ohio; Ondée; Ortho; Owen; Parke-Davis; Pennwalt; Pentagone; Pfizer; Pharmacia; Procter & Gamble; Purdue Frederick; Reed & Carnrick; Rh Institute; Rhône-Poulenc; Riker; Robins; Rorer; Ross; Rougier; Roussel; Roy; Sabex; Sandoz; Sands; Schering; Searle; Servier; Smith Kline & French; Squibb; Sterling; Stiefel; Syntex; TransCanada Dermapeutics; Unimed; Upjohn; U.S. Ethicals; USV; Webber; Welcker-Lyster; Westwood; Winthrop; Wyeth.

Editorial Advisory Panel

General Considerations

The inclusion of monographs of a company's products in the CPS does not imply that the Editors or the Editorial Advisory Panel accept, endorse or recommend these preparations as being clinically superior to similar products of any other firm.

Although the CPS lists products of various manufacturers, no attempt has been made to evaluate the therapeutic equivalence of these products or their formulations. Therapeutic efficacy may depend upon the amount of drug present in each dose, the pharmaceutical form, the physical nature of the active drug used, the presence or absence of other substances, the method of manufacture and the exercise of quality control through all stages of preparation to finished product.

The monographs are based upon information received from the manufacturers and the Health Protection Branch (HPB). They include those products available for use to meet the needs of professional practice. Products registered under the Food and Drug Regulations, Division 10, which are offered to the public for self-medication, have not been included.

For purposes of editorial style and presentation, product information as published in the CPS is not necessarily identical with that which appears in the Official Product Monograph of the HPB. It is recognized that additional information, based upon independent studies published in the literature, may be valuable to CPS users. Consequently, information presented in the monographs may not be limited solely to that currently available from the HPB.

In the monograph section, when appropriate, (and not including the general monographs), products are alphabetically listed by names which are registered trademarks of the company whose name, in full or in abbreviated

form, immediately follows it. In these cases, the designation ® appears beside the product name. CPS users are cautioned regarding the unauthorized use of any listed name. The monographs are intended to present unbiased, factual information on drugs in a format which will be useful to health care practitioners. For additional product information, readers are referred to the pertinent scientific and professional literature, to the descriptive literature of the company concerned, or to its professional personnel.

Great care has been taken to ensure the accuracy and completeness of the information contained in the CPS. However, the editors and publishers cannot be responsible for errors in publication or any consequences whatsoever arising from the use of the information published herein.

Comments concerning the CPS '82, and its usefulness to the practitioners of the various health professions, and suggestions for the improvement of future editions will be welcomed.

Errata

Serious dosage errors, or errors which threaten the patient's safety, or those which could have serious consequences will be considered for an errata. In this event, an immediate letter of correction or an appropriate insert will be sent to all known subscribers of the CPS.

Minor errors, which do not have an impact on health care, will be corrected in the next edition of the CPS.

In some cases, appropriate journals such as the Canadian Pharmaceutical Journal and the Canadian Medical Association Journal will be used to convey changes which are not urgent or serious.

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Monographs of Pharmaceuticals and Specialties

A and D OINTMENT *Schering*

Vitamins A & D—Lanolin Compound

Emollient

Indications: Diaper rash, minor skin irritations, chafing, mild sunburn, minor burns, scalds, abrasions and skin dryness.

Dosage: Apply liberally, as needed to affected skin area. Cover with suitable dressing if required.

Supplied: Each g contains: vitamin A 1,500 I.U and vitamin D 213 I.U. in a lanolin petrolatum base. Available in 25 and 75 g tubes and 450 g jars.

ABBOKINASE® *Abbott*

Urokinase ***Thrombolytic Agent***

Pharmacology: Urokinase is an enzymatic activator that acts on the endogenous fibrinolytic system. It rapidly converts plasminogen to plasmin, the proteolytic enzyme that lyses formed fibrin clots.

I.V. infusion of urokinase is followed by increased fibrinolytic activity. This effect disappears within a few hours after discontinuation of the infusion, but a decrease in plasma levels of fibrinogen and plasminogen and an increase in the amount of circulating fibrinogen degradation product (FDP/fdp) which themselves possess an anticoagulant effect may persist for 12 to 24 hours.

The majority of infused urokinase is excreted in the urine, either unchanged or as metabolites.

In controlled clinical studies, urokinase with subsequent heparin therapy, produced significantly more rapid and greater resolution of pulmonary emboli during the first 24 hours of therapy than heparin therapy given alone. This was shown by significant changes in pulmonary angiograms, perfusion lung scans, and pulmonary arterial and right heart pressure measurements. Urokinase and subsequent heparin therapy did not reduce significantly the recurrence rate of pulmonary embolism or the 2 week mortality rate, when compared with heparin therapy given alone.

Indications: The treatment of acute massive pulmonary embolism, defined as obstruction or significant filling defects involving 2 or more lobar pulmonary arteries or an equivalent amount of emboli in other vessels as seen on pulmonary arteriography; pulmonary embolism accompanied by unstable hemodynamics, e.g., inability to maintain blood pressure without supportive measures.

Contraindications: Patients who are allergic to any of the components.

Warnings: Where a surgical procedure has taken place within the previous 10 days (liver or kidney biopsy, lumbar punctures, thoracentesis or paracentesis, arteriography, extensive or multiple cutdowns); in the presence of large denuded areas or extensive unhealed skin flaps, such as may occur with extensive skin grafting or as a result of a mastectomy; if there is a history of cardiopulmonary resuscitation with chest massage within the previous 10 days; if a major arterial puncture (e.g., translumbar, femoral, carotid) has occurred within the previous 24 hours; if there has been a cerebrovascular accident or an intracranial operation within the previous 2 months, or if there is evidence of a lesion known or suspected to be associated with intracranial hemorrhage; in the presence of severe hypertension in the presence of an actively bleeding lesion (or one with a significant potential for bleeding) of the gastrointestinal or genitourinary tract; in the presence of any bleeding state, including one that may be caused by a coagulation factor deficiency, thrombocytopenia, spontaneous fibrinolysis, or another purpuric or hemorrhagic disorder; in the presence of bacterial endocarditis or rheumatic disease; in the presence of acute or chronic hepatic or renal insufficiency; in the presence of primary or metastatic intracranial malignancy; in the presence of chronic lung disease with cavitation; in the presence of any other condition in which bleeding might constitute a significant hazard or be particularly difficult to manage because of its location; during pregnancy and the first 10 days of the postpartum period.

In the presence of a pulmonary embolism which is regarded as life threatening, the conditions listed above should not be regarded as absolute contraindications. The risks of hemorrhage must be weighed carefully against the anticipated benefits of urokinase therapy, and the benefits and risks associated with surgical embolectomy as an alternate form of therapy.

Bleeding is the principal risk associated with the use of urokinase (see Adverse Effects). Because of the potential seriousness of complications from fibrinolytic therapy, patients should be treated by physicians adequately experienced with thromboembolytic disease and in hospitals or other facilities equipped to monitor and control hemorrhagic disturbances.

Moderate decreases in hematocrit, not accompanied by clinically detectable bleeding or evidence of hemolysis, have been observed in some patients. These reductions are unexplained.

Concurrent use of anticoagulants with urokinase is hazardous. Before beginning urokinase infusion in patients being treated with heparin the effects of heparin should be allowed to decrease to less than twice normal as evidenced by standard laboratory tests. Similarly, heparin should be withheld following urokinase therapy until the thrombin time is less than twice normal.

Rethrombosis has been observed after completion of urokinase treatment. In order to minimize this risk, administration of i.v. heparin followed by oral anticoagulant therapy is considered a necessary adjunct following urokinase therapy (see Dosage).

Precautions: Patients should be observed for any signs of bleeding. Hematocrit should be monitored during and following an infusion of urokinase, Invasive procedures should be kept to a minimum during the period of urokinase infusion.

Although urokinase is a protein of human origin, and in vitro tests with the drug gave no evidence of induced antibody formation, the possibility of serious allergic reactions (including anaphylaxis) occurring with its use cannot be excluded. Drugs that may alter platelet function, e.g., ASA, indomethacin, sulfinpyrazone and phenylbutazone, should be avoided during urokinase treatment. The interaction of urokinase for injection with other drugs has not been studied in humans.

Urokinase is not recommended for use during pregnancy and the first 10 days of the postpartum period (see Warnings).

Because of lack of sufficient clinical experience in children, urokinase is not recommended for patients weighing less than 37 kg.

In the elderly the dosage should be decreased and cautious observation exercised due to reduced metabolic and renal clearance.

Adverse Effects: Approximately 50% of the patients with pulmonary embolism treated during the controlled clinical trials experienced some degree of clinically detectable bleeding; bleeding occurred most often at cutdown sites. However, only 19% of the patients treated with urokinase required a blood transfusion; 8% required a blood transfusion of more than 2 units.

A moderate decrease in hematocrit, not accompanied by clinically detectable bleeding, occurred in approximately 1 out of 5 patients treated with urokinase. Febrile reactions occurred in approximately 2 to 3 out of 100 patients. Other allergic reactions, e.g., bronchospasms and skin rash, were reported rarely.

Overdose: Symptoms; Overdosage may result in severe hemorrhage, with decreased hemoglobin and hematocrit, decreased plasma levels of plasminogen and fibrinogen, and an increased amount of fibrinogen/fibrin degradation products (FDP/fdp). I.V. antihistamines and supportive treatment is recommended.

Treatment: Management of severe bleeding: Urokinase therapy must be discontinued if serious bleeding occurs. Packed red cells are indicated for large blood loss. Plasma volume expanders (other than Dextran) may be used to replace blood volume deficit. Whole blood may also be used if it alone is available.

Mild external bleeding is usually controlled by the application of local pressure.

Dosage: Abbokinase is intended for i.v. infusion only. A priming dose of 4,400 IU/kg of urokinase is given as the Abbokinase-Sodium Chloride Injection USP admixture over a period of 10 minutes. This is followed by a continuous infusion of 4,400 IU/kg/hr of urokinase (given as the Abbokinase-Sodium Chloride Injection USP admixture) for 12 hours. The total volume of fluid administered should not exceed 200 mL.

At the end of urokinase infusion, treatment with heparin by continuous i.v. infusion followed by oral anticoagulant therapy is recommended to minimize rethrombosis. Heparin treatment should begin when the thrombin time has returned to less than twice normal.

Supplied: Each vial contains: 250,000 IU urokinase activity, 25 mg mannitol and 45 mg sodium chloride as a sterile lyophilized preparation. Store the powder at 2 to 8°C.

Reviewed 1982

ABDEC® *P.D.*

Multivitamins ***Dietary Supplement***

For prescribing information, refer to "Vitamin Compounds — Oral — Liquid" and "Solid Dosage Forms".

ACCELERASE® *Organon*

Pancrelipase Compound

Enzymes—Digestant

Supplied: Each gray capsule contains: pancrelipase equivalent to 4,000 USP Lipase units, 15,000 USP Amylase units, 15,000 USP Protease units, mixed conjugated bile salts 65 mg, cellulase 2 mg. Bottles of 60 and 1,000 capsules.

(Shown in Product Recognition Section)

ACET-AM® Preparations *Organon*

Theophylline Preparation ***Bronchodilator***

Supplied: Liquid: Each 5 mL contains: theophylline sodium aminoacetate 100 mg (equivalent to theophylline 50 mg). Alcohol 20%. Available in 250 mL bottles.

Tablets: Each white compressed tablet contains: theophylline calcium aminoacetate 325 mg (equivalent to 165 mg of anhydrous theophylline). Bottles of 100, 500 and 1,000 tablets.

(Shown in Product Recognition Section)

ACET-AM® ELIXIR Preparations *Organon*

Theophylline-Sodium Aminoacetate-Ephedrine ***Bronchodilator***

Supplied: Acet-Am Elixir: Each 5 mL of elixir contains: theophylline sodium aminoacetate 100 mg, (equivalent to theophylline 50 mg), ephedrine HCl 3.5 mg, diphenhydramine HCl 12.5 mg. Alcohol 20%. Available in 250 mL bottles.

Acet-Am Elixir Plus: Each 5 mL contains: same components as Acet-Am Elixir plus guaifenesin 100 mg. Available in 250 mL bottles.

ACET-AM® EXPECTORANT *Organon*

Theophylline Sodium Aminoacetate—Guaifenesin ***Bronchodilator - Expectorant***

Supplied: Each 5 mL of expectorant contains: theophylline sodium aminoacetate 100 mg (equivalent to theophylline 50 mg), guaifenesin 100 mg, alcohol 20%. Available in 250 mL bottles.

ACETAMINOPHEN

Paracetamol ***Analgesic—Antipyretic***

Pharmacology: Acetaminophen is the major metabolite of phenacetin and acetanilid. Animal and clinical studies have shown acetaminophen to have antipyretic and analgesic activity equal to that of ASA.

Unlike the salicylates, acetaminophen does not interfere with tubular secretion of uric acid, nor does it affect acid base balance in normal therapeutic doses. Acetaminophen does not interfere with hemostasis and does not inhibit platelet aggregation.

Acetaminophen is rapidly and completely absorbed from the gastrointestinal tract. Approximately 85% of a 1 g dose is recovered from the urine in 24 hours. About 3% is excreted unchanged, the balance being conjugated principally to the glucuronide or sulfate. Peak plasma concentrations of the free and conjugated drug are achieved ½ to 1 hour after administration. The plasma half life of the unchanged drug is about 2 hours.

Allergic reactions are rare with acetaminophen but have occurred. This drug may be useful in asthmatic patients sensitive to salicylates; however, patients with salicylate induced urticaria or angioedema can suffer cross reactivity with acetaminophen.

Small amounts of acetaminophen are normally converted to a highly reactive metabolite by hepatic microsomal enzymes. At therapeutic doses, the small amounts of the active metabolite so formed are rapidly inactivated by hepatic glutathione and removed by renal excretion. However, where hepatic glutathione has been rapidly depleted by a large dose of acetaminophen, covalent binding of the metabolite to liver-cell macromolecules occurs and is presumed to be responsible for the hepatic cell necrosis. Prompt administration of acetylcysteine is indicated to prevent acetaminophen induced hepatic necrosis (see Overdose section).

Indications: The treatment of mild to moderate pain and the reduction of fever.

Contraindications: Hypersensitivity to acetaminophen.

Adverse Effects: The incidence of gastrointestinal upset is less than after salicylate administration.

Hepatic toxicity has been associated with acetaminophen overdose. Phenobarbital increases the activity of microsomal enzymes which produce a toxic metabolite and therefore acetaminophen's hepatotoxicity may be enhanced. Thus, concomitant ingestion of phenobarbital may increase the likelihood of liver necrosis in acetaminophen overdose. The chronic ingestion of alcohol may be implicated in the increasing potential for hepatic toxicity. Abnormal liver function has been associated with therapeutic doses ranging from 3 to 8 g per day. In patients with compromised liver function, acetaminophen could exacerbate liver insufficiency.

Renal papillary necrosis has been reported following prolonged acetaminophen administration of up to 19 g per day. There have been no authenticated reports of renal papillary necrosis with therapeutic doses of acetaminophen alone. Renal insufficiency may occur as an effect secondary to liver failure.

Anemia has been reported in patients with gastrointestinal bleeding who were often analgesic abusers, had chronic gastric ulcers or where gastrointestinal bleeding was already present. Neutropenia, methemoglobinemia and thrombocytopenia have rarely occurred.

Rarely, asthmatic attacks have been precipitated by acetaminophen.

Skin rashes and fixed dermatitis with pruritis have been rarely reported.

Overdose: In adults, hepatotoxicity may occur after ingestion of a single dose of 10 to 15 g (200 to 250 mg/kg) of acetaminophen; a dose of 25 g or more is potentially fatal.

Reports have indicated hepatic necrosis with a single dose of 6 g and death occurring with a single dose of 13 g. Non fatal overdoses of 12.5 to 31.5 g have also been reported. However, it is generally agreed that consumption of more than 50% of the toxic dose, e.g., 7.5 g in adults and 140 to 150 mg/kg in children could initiate liver damage.

Symptoms: The earliest symptoms of overdose with acetaminophen are nausea, vomiting, sweating and pallor. This initial period is frequently followed by an asymptomatic phase of 24 to 48 hours after which hepatic damage may become evident. Elevation in hepatic enzymes, SGOT, SGPT are noted. BUN remains low. Hepatic function is altered as measured by bilirubin and prothrombin time. The liver enlarges with marked right upper quadrant pain and tenderness.

After 3 to 5 days, jaundice, hypoglycemia, encephalopathy, cardiomyopathy, renal failure, hepatic coma and death may occur.

Factors contributing to an accurate evaluation of toxicity include: the amount of drug ingested and more significantly, the serum acetaminophen concentration measured optimally, after 4 hours of ingestion.

When serum determinations of acetaminophen are above 150 μg/mL at 4 hours, or above 40 μg/mL at 12 hours following the estimated time of ingestion, the patient is at risk of liver damage and antidotal therapy should be instituted immediately.

An additional reliable indicator of possible hepatic injury is the serum half life. The normal half life of acetaminophen in a healthy adult is 2 hours. If the serum half life exceeds 4 hours, it can be assumed that hepatic necrosis will occur; if the half life exceeds 12 hours hepatic coma is a likely possibility.

Treatment of acetaminophen overdosage includes ipecac induced emesis or gastric lavage which should, when possible, commence within 4 hours of drug ingestion. Activated charcoal is effective only when given within 1 to 2 hours of the alleged overdose. Prior to antidotal treatment with acetylcysteine (Mucomyst) residual activated charcoal must be removed by gastric lavage with water.

Acetylcysteine is effective orally. A loading dose of 140 mg/kg is given as a single dose. A maintenance dose of 70 mg/kg is then given every 4 hours for 17 doses. If nausea and vomiting occurs within 1 hour of the loading or maintenance dose, the entire dose should be repeated. If nausea and vomiting persist, a nonphenothiazine antiemetic e.g. dimenhydrinate, may be administered. Acetylcysteine 20% solution may be diluted to a 5% concentration with a soft drink or fruit juice to make it more palatable. This mixture should be consumed within 1 hour of preparation.

The use of i.v. acetylcysteine is recommended when oral therapy is not feasible or practical. A loading dose, 150 mg/kg of sterile Mucomyst 20% is infused in 200 mL D5w over 15 mins., followed by an infusion of 50 mg/kg in 500 ml D5w over 4 hours, and finally 100 mg/kg in 1000 ml D5w during the next 16 hours. The total dose is 300 mg/kg administered over 20 hours.

Dosage: Adults and Children over 10 years: 325 to 650 mg 4 to 6 times daily as necessary. Usual range: 325 mg to 2.6 g daily. Children: The following amounts, or 175 mg/m² of body surface, administered 4 times daily; under 1 year, 15 to 60 mg; 1 to 3 years, 60 to 120 mg; 3 to 6 years, 120 mg; 6 to 12 years, 150 to 300 mg.

Suppliers: Apotex (Apo-Acetaminophen); Clark; Frosst (Exdol and Exdol Strong); Horner (Atasol and Atasol Forte); Johnson & Johnson (Tylenol); Mead Johnson (Tempra—May 1957); Pro Doc; Robins (Robigesic); Rougier (Rounox); Winthrop (Campain®—1972).

Reviewed 1982

ACETAZOLAM Ⓟ *ICN*

Acetazolamide ***Carbonic Anhydrase Inhibitor***

Indications: To decrease ocular aqueous humor secretion in glaucoma (chronic, simple and secondary types). Also used as an adjunct in the treatment of selected cases of epilepsy. To alkalinize the urine in selected cases of salicylate overdosage.

Contraindications: Depressed sodium and/or potassium blood levels, in renal failure, adrenal gland failure, metabolic acidosis, and some cases of hepatic cirrhosis, severe glaucoma due to peripheral anterior synechias or in hemorrhagic glaucoma. Longterm use in chronic noncongestive angle closure glaucoma is contraindicated.

Studies on acetazolamide in mice and rats have consistently demonstrated embryocidal and teratogenic effects at doses in excess of 10 times the human dose. There is no evidence of these effects in humans; however, acetazolamide should not be used in pregnancy, unless the anticipated benefits outweigh these potential hazards and are not attainable in other ways.

Precautions: Increasing the dose does not increase and may often decrease the diuresis and may yet produce drowsiness and/or paresthesia.

Adverse Effects: Metabolic acidosis and hypokalemia may occur during prolonged acetazolamide therapy.

Adverse reactions common to all sulfonamide derivatives including fever, rash, crystalluria, renal calculus, bone marrow depression, thrombocytopenic purpura, hemolytic anemia, leukopenia, pancytopenia and agranulocytosis may occur. If such reactions occur, discontinue therapy and institute appropriate measures.

Untoward effects during short term therapy are said to be minimal. Those noted include paresthesias, some loss of appetite, polyuria and occasional instances of drowsiness and confusion. Other occasional adverse reactions include urticaria, melena, hematuria, glycosuria, hepatic insufficiency, flaccid paralysis and convulsions.

Transient myopia has been reported. This condition invariably subsided upon the diminution or discontinuation of the medication.

Dosage: Chronic simple (open angle) glaucoma: 250 mg 1 to 4 times daily. A complementary effect has been noted when acetazolamide was used with miotics or mydriatics as the case demanded. Secondary glaucoma and preoperative treatment of some cases of acute congestive (closed angle) glaucoma: 250 mg every 4 hours. Epilepsy: 8 to 30 mg/kg (375 to 1,000 mg) daily in divided doses. To alkalinize the urine: 250 mg every 4 to 6 hours.

Supplied: Each white, scored, compressed tablet contains: acetazolamide USP 250 mg. Bottles of 100 and 500 tablets.

ACETEST® *Ames*

Sodium Nitroprusside Reagent

Ketonuria Diagnostic Aid

Indications: Detection of acetone and acetoacetic acid in urine, serum, plasma or whole blood.

Precautions: Specimens containing Urofix as a urine preservative will produce an atypical gray color. Bromsulphalein or high concentrations of phenylketones will cause color reactions with Acetest tablets. Results should not be interpreted under fluorescent lighting only.

Method of Use: Place tablet on a clean sheet of paper, add 1 drop of urine to tablet and wait 30 seconds to compare reaction with color chart provided. Trace, moderate or strongly positive reactions are indicated by color range of lavender to deep purple.

Overdose: Symptoms: If accidentally ingested, symptoms are those of borate poisoning.

Treatment: Gastric lavage.

Supplied: Reagent tablets containing: sodium nitroprusside, sodium borate, disodium phosphate, glycine and lactose. Bottles of 100 and 250 reagent tablets.

ACETOPHEN® *Frosst*

ASA ***Analgesic—Antipyretic—Anti-inflammatory***

Pharmacology: See ASA monograph.

Indications: The relief of pain, fever and inflammation in a variety of conditions such as influenza, common cold, low back and neck pain, dysmenorrhea, headache, toothache, sprains and strains, fractures, myositis, neuralgia, synovitis, arthritis, bursitis, burns, injuries, following surgical and dental procedures.

Contraindications: Salicylate sensitivity, active peptic ulcer.

Warnings: ASA is one of the most frequent causes of accidental poisoning in toddlers and infants. Therefore, keep salicylates well out of children's reach.

Precautions: Administer salicylates cautiously to patients with asthma and other allergic conditions, a history of gastrointestinal ulcerations, bleeding tendencies, significant anemia, or hypoprothrombinemia.

Patients taking 2 to 3 g of ASA daily are at an increased risk of developing severe gastrointestinal bleeding following the ingestion of alcohol.

If possible, uncoated ASA tablets should not be swallowed whole but should be well chewed and followed with an adequate volume of water or crushed into a fine powder and taken as a suspension in orange juice.

Since salicylates interfere with maternal and infant blood clotting and lengthen the duration of pregnancy and parturition time, they should not be administered during the last trimester of pregnancy unless the need outweighs the potential risks.

Caution is necessary when salicylates and anticoagulants are prescribed concurrently, as salicylates can depress the concentration of prothrombin in the plasma.

Patients receiving concurrent salicylate hypoglycemic therapy should be monitored closely, and reduction of the hypoglycemic drug dosage may be necessary.

Although salicylates in large doses are uricosuric agents, smaller amounts may depress uric acid clearance and thus decrease the uricosuric effects of probenecid, sulfinpyrazone, oxyphenbutazone and phenylbutazone.

Exercise caution when corticosteroids and salicylates are used concurrently.

Acute hepatitis has been reported rarely in patients with systemic lupus erythematosus and juvenile rheumatoid arthritis with plasma salicylate concentrations above 25 mg/100 mL. Patients have recovered upon cessation of therapy.

Restrict salicylate ingestion in patients receiving indomethacin (and perhaps other nonnarcotic analgesics) for conditions such as rheumatoid arthritis.

Salicylates can produce changes in thyroid function tests.

Sodium excretion produced by spironolactone may be decreased by salicylate administration.

Concomitant ingestion of salicylates and aminosalicylic acid (PAS) or aminobenzoic acid (PABA) in normal dose may lead to increased toxicity and salicylism.

Salicylates reportedly displace sulfonylureas, penicillins and methotrexate from their binding sites on plasma proteins. Salicylates also retard the renal elimination of methotrexate.

Adverse Effects: Gastrointestinal: nausea, vomiting, diarrhea, gastrointestinal bleeding and/or ulceration.
Ear: tinnitus, vertigo, hearing loss.
Hematologic: leukopenia, thrombocytopenia, purpura.
Dermatologic and hypersensitivity: urticaria, angioedema, pruritus, skin eruptions, asthma, anaphylaxis.
Miscellaneous: acute, reversible hepatotoxicity; mental confusion, drowsiness, sweating, thirst.

Overdose: Symptoms: In mild overdosage these may include rapid and deep breathing, nausea, vomiting (leading to alkalosis), hyperpnea, vertigo, tinnitus, flushing, sweating, thirst and tachycardia. (High ASA blood concentrations lead to acidosis). Severe cases may show fever, hemorrhage, excitement, confusion, convulsions or coma, and respiratory failure.

Treatment is essentially symptomatic and supportive. Administer water, activated charcoal and remove by cautious gastric lavage or emesis. Force fluids and replace sodium loss. If the patient is unable to retain fluids orally, the alkalosis can be treated by i.v. hypertonic saline. If salicylism acidosis is present, i.v. sodium bicarbonate is preferred because it increases the renal excretion of salicylates. Vitamin K is indicated if there is evidence of hemorrhage. Dialysis has been used with success.

Use general supportive measures for depressed respiration e.g. oxygen and artificial respiration. Convulsions may best be treated by the administration of succinylcholine and artificial ventilation with oxygen. Do not use CNS depressant agents. Hyperthermia and dehydration are immediate threats to life and initial therapy must be directed to their correction and to the maintenance of adequate renal function. External cooling with cool water or alcohol should be provided quickly to any child who has a rectal temperature over 40° C.

Dosage: Adults—Analgesic/antipyretic: 650 mg 4 to 6 times a day as necessary.
Anti-inflammatory: 1 g 4 to 6 times a day, up to 10 g daily.
Usual dosage range: 325 mg to 10 g daily.
Children—Analgesic/antipyretic: 11 mg/kg or 250 mg/m² of body surface, 6 times a day to 16 mg/kg or 375 mg/m² of body surface, 4 times a day. Maximum daily dose is 3.6 g.
Anti-inflammatory: 16 mg/kg 6 times a day or 25 mg/kg 4 times a day initially (up to 125 mg/kg/day). After complete relief of symptoms in the absence of signs of toxicity, reduce the dose to 10 mg/kg 6 times a day or 15 mg/kg 4 times a day (up to 100 mg/kg/day).

Supplied: Each white tablet engraved with F symbol contains: ASA 325 mg. Bottles of 1,000 tablets.

(Shown in Product Recognition Section)

ACETOPHEN® COMPOUNDS *Frosst*

Tablets of ACETOPHEN® (ASA) and various combinations—e.g. 217, 222, 282, 292, 283, 692, etc., refer to Numbers Index.

. . . Drug identification problem? Consult the PRODUCT RECOGNITION SECTION of CPS.

ACETOXYL® 2.5% and 5% GEL
ACETOXYL® 10% and 20% GEL ℞
Stiefel

Benzoyl Peroxide Compound

Acne Vulgaris Therapy

Indications: Topical treatment of acne vulgaris.

Contraindications: Known hypersensitivity to any of the components, presence of eczema or seborrheic dermatitis. Use on patients with very blond (albino) skin is not recommended.

Precautions: Keep away from eyes or mucous membranes. Transitory stinging or burning sensation on initial application invariably disappears on continued use. May cause irritation on neck, circumoral and other sensitive areas. If excessive dryness, irritation or sensitivity occurs, discontinue use temporarily. Acetoxyl may bleach hair and colored fabrics.

Radiation from ultraviolet and cold quartz sources as well as abrasion may add to the desquamative effect produced by benzoyl peroxide and, therefore, should be reduced in intensity and/or frequency during treatment.

Very fair individuals should always be started with a single application of Acetoxyl 2.5 at bedtime.

Adverse Effects: Allergic contact dermatitis and severe erythema with crusting have been reported with topical benzoyl peroxide. Do not confuse a strong irritant reaction with allergic sensitivity. Patch testing should be employed to confirm sensitivity.

Dosage: Apply once daily to affected areas as prescribed. For best results, wash face with soap and water prior to application.

Supplied: Each plastic tube contains benzoyl peroxide 2.5% (Acetoxyl 2.5), 5% (Acetoxyl 5), 10% (Acetoxyl 10) or 20% (Acetoxyl 20) in an acetone gel base. Available in 60 g tubes. Store at room temperature.

ACETYLSALICYLIC ACID
See ASA

ACHROCIDIN® ℞ *Lederle*

Tetracycline-Salicylamide Compound

Antibiotic—Analgesic

Indications: The treatment of tetracycline sensitive bacterial infection which may complicate vasomotor rhinitis, sinusitis and other allergic diseases of the upper respiratory tract, and for the concomitant symptomatic relief of headache and nasal congestion.

Contraindications, Precautions and Adverse Effects: As for Achromycin. Patients should be cautioned not to operate vehicles or hazardous machinery until their response to the drug has been determined. Since the depressant effects of antihistamines are additive to those of other drugs affecting the CNS, patients should be cautioned against drinking alcoholic beverages or taking hypnotics, sedatives, pyschotherapeutic agents or other drugs with CNS depressant effects during antihistamine therapy.

Dosage: Adults, 2 tablets, with water at onset of symptoms, then 2 tablets 3 or 4 times daily for 3 to 5 days. Children, dosage is determined by the tetracycline content on the basis of 22 to 44 mg tetracycline/kg per day.

Oral forms of tetracycline should be given 1 hour before or 2 hours after meals. Antacids, containing aluminum, calcium or magnesium and iron salts impair absorption and should not be given to patients taking oral tetracyclines. Foods and some dairy products also interfere with absorption.

Supplied: Each yellow, coated tablet contains: tetracycline HCl 125 mg, caffeine 30 mg, salicylamide 300 mg, chlorothen citrate 25 mg. Bottles of 100 and 500 tablets.

ACHROMYCIN® Preparations ℞
Lederle

Tetracycline HCl ***Antibiotic***

Pharmacology: see tetracycline monograph.

Indications: Many strains of bacteria have been shown to be resistant to the tetracyclines. These include certain strains of streptococci, staphylococci, pneumococci, gonococci, and many other gram negative organisms. Therefore, culture and sensitivity testing are advised to determine the susceptibility of the infecting organisms to tetracyclines. Chemotherapy should not be initiated until all the necessary bacteriological investigations have been started.

Microorganisms that have become insensitive to one tetracycline invariably exhibit cross resistance to other tetracyclines.

Some cross resistance between the tetracyclines and chloramphenicol for gram negative organisms but not for gram positive ones has been reported. Tetracycline resistant organisms are most likely to be acquired from other individuals in a population where tetracycline has been widely used.

The tetracyclines are indicated in infections caused by the following microorganisms:

Rickettsiae (Rocky Mountain spotted fever, typhus fever and the typhus group, Q fever, rickettsialpox, tick fevers). M. pneumoniae (PPLO, Eaton agent), agents of psittacosis and ornithosis, agents of L. venereum and G. inguinale, and the spirochetal agent of relapsing fever (B.recurrentis).

The following gram negative organisms: H. ducreyi (chancroid), P. pestis and P. tularensis, B. bacilliformis, Bacteroides, V. comma and V. fetus, and Brucella organisms (in conjunction with streptomycin).

The following gram negative organisms, when bacteriologic testing indicates appropriate susceptibility to the drug: E. coli, E. aerogenes, Shigella, Mima, Herellea, H. influenzae (respiratory infections), and Klebsiella infections (respiratory and urinary).

The following gram positive organisms when bacteriologic testing indicates appropriate susceptibility to the drug: anaerobic streptococci, S. pyogenes (For upper respiratory infections due to Group A beta hemolytic streptococci, penicillin is the drug of choice including prophylaxis of rheumatic fever), S. pneumoniae, and S. aureus. The frequency of resistance to tetracyclines in hemolytic streptococci is highest in strains from infections of the ear, wounds and skin. Tetracyclines should not be prescribed for acute throat infections; also, they are not the drug of choice in any staphylococcal infection.

When penicillin is contraindicated, tetracyclines are alternative drugs in the treatment of infections due to: N. gonorrhoeae, T. pallidum and T. pertenue (syphilis and yaws), L. monocytogenes, Clostridia, B. anthracis, Fusobacterium (Vincent's infection), and Actinomyces.

In acute intestinal amebiasis, the tetracyclines may be a useful adjunct to amebicides. In severe acne the tetracyclines may be useful adjunctive therapy.

Tetracyclines are indicated in the treatment of trachoma, although the infectious agent is not always eliminated, as judged by immunofluorescence.

Inclusion conjunctivitis may be treated with oral tetracyclines or with a combination of oral and topical agents.

Because tetracycline tends to accumulate in certain neoplastic cells and to exhibit a brilliant, yellowish gold fluorescence when exposed to ultraviolet light, it may be useful in experienced hands for the diagnosis of malignancy.

Contraindications: Hypersensitivity to any of the tetracyclines; severe renal or hepatic disease.

Pregnant or lactating women unless potential benefit to patient outweighs risk to fetus or child.

Therapy of common infections in children under 12. Any condition in which bactericidal effect is essential (bacterial endocarditis).

Avoid prophylactic administration to surgical cases, if possible.

Precautions: The use of tetracyclines during tooth development (last half of pregnancy, infancy and childhood to the age of 8 years) may cause permanent tooth discoloration (yellow, gray, brown). This reaction is more common during long term use of the tetracyclines, but has been observed following short term courses. Enamel hypoplasia has also been reported. Tetracycline drugs, therefore, should not be used in this age group unless other drugs are not likely to be effective or are contraindicated.

Results of animal studies indicate that tetracyclines cross the placenta, are found in fetal tissues and can have toxic effects on the developing fetus (often related to retardation of skeletal development). Evidence of embryotoxicity has also been noted in animals treated early in pregnancy.

Tetracyclines are present in the milk of lactating women who are taking a drug in this class.

If renal impairment exists, even usual oral or parenteral doses may lead to excessive systemic accumulation of the drug and possible liver toxicity. Under such conditions, lower than usual doses are indicated and, if therapy is prolonged, serum level determinations of the drug may be advisable.

The antianabolic action of the tetracycline may cause an increase in BUN. While this is not a problem in those with normal renal function, in patients with significantly impaired function, higher serum levels of tetracycline may lead to azotemia, hyperphosphatemia, and acidosis. Consequently, increasing levels of BUN may not accurately reflect changes in renal function; the serum creatinine will provide a more reliable index.

Photosensitivity manifested by an exaggerated sunburn reaction has been observed in some individuals taking tetracyclines. Patients should be warned to avoid exposure to direct sunlight and/or ultraviolet light while under treatment with tetracycline drugs, and treatment should be discontinued at the first evidence of skin discomfort.

Tetracyclines form a stable calcium complex in any bone forming tissue. A decrease in the fibula growth rate has been observed in prematures given oral tetracycline in doses of 25 mg/kg every 6 hours. This reaction was shown to be reversible when the drug was discontinued.

Tetracycline administration may result in overgrowth of nonsusceptible organisms. Superinfections due to staphylococci and other organisms may occur during oral but rarely during parenteral administration.

C. albicans can produce effects at three levels: proliferation in the mouth can cause disturbances ranging from simple soreness to frank and extensive thrush, which may spread to the pharynx and possibly the bronchi; in the bowel, it can be manifested by diarrhea; also, pruritus ani occurs frequently.

Proteus and Pseudomonas species resistant to tetracyclines may become predominant in the bowel and diarrhea is common. Periodic microbiologic examination of materials, such as stool and sputum, during tetracycline therapy may alert one to changes in flora indicating bacteriologic superinfection in time to avert progression to clinical disease.

If superinfections are encountered, tetracyclines should be discontinued and appropriate therapy started. Superinfection of the bowel by staphylococci may be life threatening.

Adhere closely to expiration dates; ingestion of deteriorated tetracyclines has produced kidney damage corresponding clinically to the acute Fanconi syndrome (nausea, vomiting, albuminuria, glycosuria, aminoaciduria, hypophosphatemia, hypokalemia, and acidosis). Such damage is usually reversed slowly after withdrawal of the deteriorated tetracycline, although fatal reactions have been reported.

Before treating gonorrhea, a darkfield examination should be made from any lesion suggesting concurrent syphilis. Serological tests for syphilis should be made for at least 4 months afterwards.

Because the tetracyclines have been shown to depress plasma prothrombin activity, patients who are on anticoagulant therapy may require downward adjustment of their anticoagulant dosage. Interference with vitamin K synthesis by microorganisms in the gut has been reported.

Concurrent use of methoxyflurane and tetracyclines has been reported to impair renal function seriously leading in some cases to death. Such use of these two drugs is therefore not recommended unless the benefits outweigh the risks.

Since bacteriostatic drugs may interfere with the bactericidal action of penicillin, it is advisable to avoid giving tetracycline in conjunction with penicillin.

During long term therapy, periodic laboratory evaluation of organ systems, including hematopoietic, renal and hepatic studies should be performed.

All infections due to Group A beta hemolytic streptococci should be treated for at least 10 days.

Since sensitivity reactions are more likely to occur in persons with a history of allergy, asthma, hay fever, or urticaria, the preparations should be used with caution in such individuals. Cross-sensitization among the various tetracyclines is extremely common.

When it is essential to administer any of the tetracyclines i.v., the blood level should not be permitted to exceed 15 μg/mL and, if possible, other potentially hepatotoxic drugs should be avoided. Presumably, large doses may be expected to have comparable toxicity by either the i.m. or oral route if renal or hepatic insufficiency is present.

Adverse Effects: Gastrointestinal: anorexia, epigastric distress, nausea, vomiting, diarrhea, bulky loose stools, stomatitis, sore throat, glossitis, black hairy tongue, dysphagia, hoarseness, enterocolitis, and inflammatory lesions (with candidal overgrowth) in the anogenital region, including proctitis and pruritus ani. These reactions have been caused by both the oral and parenteral administration of tetracyclines but are less frequent after parenteral use.

Skin: maculopapular and erythematous rashes. Exfoliative dermatitis has been reported but is uncommon. Onycholysis and discoloration of the nails have been reported rarely. Photosensitivity has occurred (see Precautions).

Renal toxicity: rise in BUN has been reported and is apparently dose related (see Precautions).

Hepatic cholestasis has been reported rarely, and is usually associated with high dosage levels of tetracycline. Hepatic toxicity, associated with pancreatitis in some cases, has been attributed to the long term use of doses larger than those recommended in patients with renal insufficiency or to the concomitant administration of other potentially hepatotoxic drugs. This serious reaction has occurred most often in pregnant or postpartum patients with pyelonephritis.

Hypersensitivity reactions: urticaria, angioneurotic edema, anaphylaxis, anaphylactoid purpura, pericarditis, exacerbation of systemic lupus erythematosus, and serum sickness like reactions, as fever, rash, and arthralgia. When given over prolonged periods, tetracyclines have been reported to produce brownish black microscopic discoloration of thyroid glands. No abnormalities of thyroid function studies are known to occur.

Bulging fontanels have been reported in young infants following full therapeutic dosage. This sign disappeared rapidly when the drug was discontinued.

Blood: anemia, hemolytic anemia, thrombocytopenia, thrombocytopenic purpura, neutropenia and eosinophilia have been reported.

Dosage: Oral: Adults should receive an average daily dose of 250 mg 4 times a day. Higher dosages, such as 500 mg 4 times a day may be required for severe infections.

Antacids, containing aluminum, calcium or magnesium and iron salts impair absorption and should not be given to patients taking oral tetracyclines. Foods and some dairy products also interfere with absorption. Oral forms of tetracycline should be given 1 hour before or 2 hours after meals.

Parenteral: I.V. or i.m. administration should be employed only when the oral route is not practical.

I.M. —Add 2 mL of sterile water for injection USP (or sodium chloride injection USP) to the 250 mg vial. The resulting solution may

be stored at room temperature and should not be used after 24 hours. Inject deeply, either into the gluteal region or the anterior thigh. Inadvertent injection into the s.c. or fat layers may cause mild pain and induration, which can be relieved by applying an ice pack.

Infants and children: 10 mg/kg (4.5 mg/lb.) per day in divided doses. Adults: Average dose range: 200 to 300 mg daily in divided doses or a single 250 mg vial per day. In severe infections: 100 mg every 4 to 6 hours or one 250 mg vial every 12 hours.

I.V. —The vials may be initially reconstituted by adding 10 mL of sterile water for injection to the 500 mg vial. After the solution has been prepared, it should be further diluted prior to administration to at least 100 mL (up to 1,000 mL) with any of the following diluents: sterile water for injection USP; sodium chloride injection USP; dextrose injection USP; dextrose and sodium chloride injection USP; Ringer's injection USP; Lactated Ringer's injection USP; protein hydrolysate injection; low sodium USP 5%, 5% with dextrose 5%, 5% with invert sugar 10%.

The initial reconstituted solutions are stable at room temperature for 12 hours without significant loss of potency. The final dilution for administration should be administered without delay. The use of solutions containing calcium should be avoided as these tend to form precipitates (especially in neutral to alkaline solution) and, therefore, should not be used unless necessary. However, Ringer's injection, USP and Lactated Ringer's injection USP can be used with caution since the calcium ion content in these diluents does not normally precipitate tetracycline in an acid media.

The rate of infusion should not exceed 100 mL per 5 minutes. Tetracycline i.v. infusion may precede or follow, but should not accompany, a blood transfusion. The i.v. route should not be used unless the oral route is not feasible.

Usual dose is 500 mg at 12 hour intervals which should not ordinarily be exceeded unless the physician, because of the severity of the disease, wishes to increase it to a maximum of 500 mg every 6 hours. The suggested parenteral pediatric dosage for newborn and young children is 10 to 15 mg/kg/day, given in 2 doses. Because of insufficient experience in the treatment of infants under 1 month of age, caution should be exercised in administering the drug to patients in this age group.

Topical Ointment: Apply directly to the involved area preferably on sterile gauze, one or more times daily as the condition indicates. In severe local infections, systemic therapy may become necessary as prescribed.

Ophthalmic Ointment: Apply to the infected eye every 2 hours or oftener as the condition and response indicate. Severe or stubborn infections may require oral antibiotic administration in addition to local treatment.

Supplied: Injectables: I.M.: Each vial contains: tetracycline HCl 250 mg, procaine HCl 40 mg, magnesium chloride 46.84 mg, ascorbic acid 275 mg. Available in boxes of 12 vials.

I.V.: Each vial contains: tetracycline HCl 500 mg, ascorbic acid 1,250 mg. Available in boxes of 12 vials.

Topical Ointment: Each g contains: tetracycline HCl 30 mg in a wool fat petrolatum base. Available in 30 g tubes.

Ophthalmic Ointment: Each 3.5 g tube contains: 1% tetracycline HCl in a wool fat petrolatum base.

ACHROMYCIN® V Ⓡ *Lederle*

Tetracycline HCl — ***Antibiotic***

Supplied: Each blue and yellow, hard shell capsule contains: tetracycline HCl 250 mg. Bottles of 100 and 500 capsules.

For prescribing information, refer to Achromycin monograph.

ACID MANTLE® *Miles*

Aluminum Acetate — ***Dermatitis Therapy***

Indications: To restore and maintain the protective acidity of the skin. Treatment of irritated skin due to soaps, detergents, chemicals, alkalis. Useful for the treatment of diaper rash, winter eczema, and dry, rough, scaling skin.

Precautions: Limited compatibility and stability with vitamin A, neomycin and water sensitive antibiotics.

Dosage: Prophylactically after each washing of skin surface. Therapeutically as required.

Supplied: Available in cream or lotion form: formulated with buffered aluminum acetate in a water miscible base. Acid pH. Availability: **Cream:** 30 g tubes, 120 g jars. **Lotion:** 110 mL squeeze bottles. Store below 30°C. Avoid freezing.

ACIDOBYL® *Desbergers*

Biles Salts-Homatropine Compound — ***Choleretic—Antispasmodic***

Indications: Dyspepsia due to biliary deficiency. Biliary dyskinesia. Adjunct in management of infective states of gallbladder and hepatobiliary ducts.

Contraindications: Biliary tract obstruction, acute hepatitis, glaucoma, advanced renal or hepatic disease, prostatic hypertrophy, hypersensitivity to any of the components.

Precautions: Observe longterm patients periodically for signs of increased intraocular pressure.

Adverse Effects: Diarrhea, dry mouth, blurred vision and difficult urination may occur.

Overdose: Symptoms: Diarrhea, dry mouth.

Treatment: Delay absorption of ingested drug by giving water, milk or activated charcoal and then remove by gastric lavage or Ipecac Syrup USP emesis followed by catharsis. As a physiologic antidote, physostigmine may be given to reverse the central and peripheral effects of homatropine.

Dosage: 1 or 2 tablets after each meal.

Supplied: Each yellow round, biconvex, coated tablet contains: dehydrocholic acid 120 mg, bile salts 120 mg, dioctyl sodium sulfosuccinate 60 mg, homatropine methylbromide 500 µg. Bottles of 50 and 500 tablets.

(Shown in Product Recognition Section)

ACIDOBYL® with CASCARA *Desbergers*

Bile Salts-Homatropine-Cascara Compound — ***Choleretic—Laxative—Antispasmodic***

Indications: Treatment of functional gastrointestinal disorders associated with hepatobiliary stasis (chronic constipation, dyspepsia).

Contraindications, Precautions, Adverse Effects: As for Acidobyl.

Overdose: Symptoms: Diarrhea, dry mouth, pigmentation of the rectal mucosa, melena.

Treatment: As for Acidobyl.

Dosage: 1 or 2 tablets after each meal.

Supplied: Each brown, round, biconvex, coated tablet contains: dehydrocholic acid 60 mg, bile salts 120 mg, casanthranol 20 mg, dioctyl sodium sulfosuccinate 50 mg, homatropine methylbromide 500 µg. Bottles of 50 and 500 tablets.

(Shown in Product Recognition Section)

ACIDULIN® *Lilly*

Glutamic Acid HCl — ***Gastric Acidifier***

Supplied: Each No. 1, pink Pulvule capsule contains: glutamic acid hydrochloride 340 mg which is equivalent to about 10 minims of Diluted Hydrochloric Acid, NF or to about 16.8 mL of 0.1 NF hydrochloric acid. Bottles of 100 Pulvules.

Identi-Code: F 31.

For prescribing information, refer to glutamic acid monograph.

ACI-JEL® *Ortho*

Acetic-Boric Acid Compound — ***Vaginal Acidifier***

Indications: In cases where the restoration and maintenance of vaginal acidity is desirable as in the treatment of nonspecific vaginal infection and in the milder forms of simple cervicitis. Also useful prophylactically after courses of more specific therapy.

Dosage: In the average case, one applicatorful intravaginally in the morning and upon retiring. In those cases where there is a tendency to vaginal discharge or leakage, a vulvar pad is recommended. The frequency of application and duration of treatment depends upon the type of case and the degree of progress.

Supplied: Jelly: Contains: acetic acid 0.92%, oxyquinoline sulfate 0.025%, ricinoleic acid 0.7%, boric acid 3% and glycerin 5%, compounded with tragacanth, acacia, propylparaben, potassium hydroxide, stannous chloride, egg albumen, potassium bitartrate, perfume and water. Available in 85 g tubes with or without applicator.

ACNAVEEN® Treatment Bar *Cooper*

Colloidal Oatmeal-Sulfur Compound — ***Acne Therapy***

Indications: For the treatment of acne and dandruff.

Dosage: Acne: Wet face thoroughly and massage into skin vigorously to produce lather. Allow lather to remain on skin for several minutes. Rinse thoroughly. Repeat 2 or 3 times daily or as required.

Dandruff: Wet hair and scalp thoroughly. Massage into hair and scalp. Leave lather on for 5 minutes. Rinse. Repeat shampoo and rinse hair and scalp immediately. Use twice weekly, or as required.

Supplied: Each 90 g bar contains: Aveeno colloidal oatmeal, 2% sulfur and 2% salicylic acid, with sodium lauryl ester sulfonate as sudsing agent. pH: 4.8 to 6.0.

. . . Canada's Poison Control Centres are listed in full in the Gray Reference Section of CPS.

ACNE-AID® GEL *Stiefel*

Sulfur-Resorcinol Compound — ***Acne Therapy***

Indications: In acne vulgaris, and where a mild keratolytic, antiseborrheic and antimicrobial agent is required.

Contraindications: Do not apply to diffuse, acutely inflamed areas.

Precautions: Keep away from eyes and off eyelids. Should excessive dryness or irritation develop, discontinue use.

Dosage: Wash the affected part with cleanser recommended by the physician. Dry thoroughly without rubbing. Apply gel with the fingertips, allowing a thin film to remain.

Supplied: Each 15 or 50 g tube of gel contains: sulfur 2.5%; resorcinol 1.25%; chloroxylenol 0.375% with microporous cellulose in a flesh colored, gel base.

ACNE-AID® SOAP *Stiefel*

Detergent

Indications: To cleanse oily skin; open clogged pores; a shampoo for the oily scalp.

Dosage: Using warm water, massage lather on affected areas, with fingers, cloth or facial brush as indicated. Rinse warm, then cold. Repeat if skin is very oily. Dry and apply medication, if any.

Supplied: Each 100 g cake consists of a hypoallergenic blend of neutral soap and surfactant.

ACNOMEL® *SK&F*

Resorcinol-Sulfur Compound — ***Acne Therapy***

Indications: Treatment of acne: basic topical medication for acne. The cake may be used by patients who desire a medicated preparation to mask lesions during the day and by those with sensitive skin.

Contraindications: Should not be applied to diffuse, acutely inflamed areas. Keep out of eyes and off eyelids.

Precautions: Moderate erythema and scaling are normal and expected results of therapy. However, should these reactions become excessive, the patient should apply the product less frequently or discontinue until they subside.

Pharmaceutical Compatibility: Should not be diluted or compounded with other drugs. Dispense in the original container.

Overdose: Involves the skin primarily.

Symptoms: Moderate erythema and scaling are normal and expected results of therapy. Overdosage is marked by excessive drying and erythema or by burning and itching.

Treatment: Switch the patient to one half strength Acnomel cake. In severe cases, discontinue medication and apply a bland ointment or cold cream.

Accidental Ingestion: In case of accidental ingestion by children, the amount which the child succeeds in swallowing would be expected to be small, and symptoms would generally consist merely of mild gastrointestinal disturbance. Treatment consists of general measures such as inducing emesis; gastric lavage; catharsis; and forcing fluids.

Dosage: Before application, wash affected areas with soap and water, then dry.

Cake: Apply with moist sponge or finger tips, 2 or 3 times daily, as required, to treat and mask individual lesions.

Cream: Apply a thin coating with fingers. Stroke on lightly; do not rub in. One application daily is usually adequate. Patients with oily skin may apply more frequently.

Supplied: Cake (Half strength): resorcinol 1%, sulfur 4%, in a washable, flesh tinted cake base. Available in 25 g plastic containers.

Cream (Standard strength): resorcinol 2%, sulfur 8%, in a stable, greaseless, flesh tinted base. Available in 25 and 40 g tubes.

ACRIFLEX® *Glaxo*

Aminacrine HCl — ***Topical Antiseptic***

Indications: As a first aid antiseptic application to minor superficial wounds, minor burns, cuts, abrasions, scratches and as an emollient for chapped skin, sunburn, diaper rash and minor superficial skin infections.

Supplied: A non staining cream containing: aminacrine HCl 1:1,000. Available in 30 g tubes.

ACTH

Corticotropin — ***Adrenocorticotropic Hormone***

Indications: Diagnostic testing of adrenocortical function.

Corticotropin injections have limited therapeutic value in conditions responsive to corticosteroid therapy; however, corticosteroid therapy is considered to be the treatment of choice. Accordingly, corticotropin injections may be employed in the following disorders:

Rheumatic disorders: As adjunctive therapy for short term administration (to tide the patient over an acute episode or exacerbation) in psoriatic arthritis, rheumatoid arthritis, ankylosing spondylitis, acute and subacute bursitis, acute nonspecific tenosynovitis, acute gouty arthritis.

Collagen diseases: During an exacerbation or as maintenance therapy in selected cases of systemic lupus erythematosus, systemic dermatomyositis (polymyositis), acute rheumatic carditis.

Dermatologic diseases: pemphigus, bullous dermatitis herpetiformis, severe erythema multiforme (Stevens-Johnson syndrome), exfoliative dermatitis, severe psoriasis.

Allergic states: Control of severe or incapacitating allergic conditions intractable to adequate trials of conventional treatment—seasonal or perennial allergic rhinitis, bronchial asthma, contact dermatitis, atopic dermatitis, serum sickness.

Ophthalmic diseases: severe acute and chronic allergic and inflammatory processes involving the eye and its adnexa such as allergic conjunctivitis, keratitis, herpes zoster ophthalmicus, iritis, diffuse posterior uveitis and choroiditis, optic neuritis, sympathetic ophthalmia.

Respiratory diseases: symptomatic sarcoidosis, Loeffler's syndrome not manageable by other means, berylliosis.

Hematologic disorders: acquired (autoimmune) hemolytic anemia.

Neoplastic diseases: palliative management of adult leukemias and lymphomas, acute leukemia of childhood.

Edematous state: To induce a diuresis or a remission of proteinuria in the nephrotic syndrome without uremia of the idiopathic type or that due to lupus erythematosus.

Miscellaneous: tuberculous meningitis with subarachnoid block or impending block when concurrently accompanied by appropriate antituberculous chemotherapy, trichinosis of neurologic or myocardial involvement.

Contraindications: Scleroderma, osteoporosis, systemic fungal infections, ocular herpes simplex, recent surgery, history of or the presence of a peptic ulcer, congestive heart failure, hypertension, sensitivity to proteins of porcine origin.

Treatment of conditions listed within the "Indications" section when they are accompanied by primary adrenocortical insufficiency or adrenocortical hyperfunction.

Administration of i.v. corticotropin is contraindicated for treatment of conditions listed within the "Indications" section.

Precautions: Chronic corticotropin administration may lead to irreversible adverse effects. Corticotropin may only suppress symptoms and signs of chronic disease without altering the natural course of the disease. Do not administer corticotropin for treatment until adrenal responsiveness has been verified with the route of administration which will be utilized during treatment. A rise in urinary and plasma corticosteroid values provides direct evidence of a stimulatory effect. Prolonged corticotropin administration increases the risk of hypersensitivity reactions.

Although the action of corticotropin is similar to that of exogenous adrenocortical steroids, the quantity of adrenocorticoid may be variable. In patients who receive prolonged corticotropin therapy, the additional use of rapidly acting corticosteroids before, during, and after an unusual stressful situation is indicated.

Prolonged use of corticotropin may produce posterior subcapsular cataracts and glaucoma with possible damage to the optic nerves.

Corticotropin may mask some signs of infection, and new infections including those of the eye due to fungi or viruses may appear during its use. There may be decreased resistance and inability to localize infection when corticotropin is used.

Since fetal abnormalities have been observed in experimental animals, use of corticotropin in pregnancy, nursing mothers, or women of childbearing potential requires that the potential benefits of the drug be weighed against the potential hazards to the mother and embryo or fetus. Infants born of mothers who have received substantial doses of corticotropin during pregnancy should be carefully observed for signs of hypoadrenalism and appropriate therapy instituted if such signs are present.

Corticotropin can cause elevation of blood pressure, salt and water retention and increased potassium excretion. Dietary salt restriction and potassium supplementation may be necessary. Corticotropin increases calcium excretion.

While on corticotropin therapy, do not vaccinate patients against smallpox. Undertake other immunization procedures with caution in patients who are receiving corticotropin, especially when high doses are administered because of the possible hazard of neurological complications and lack of antibody response.

Patients with latent tuberculosis or tuberculin reactivity who receive corticotropin should be closely observed as reactivation of the disease may occur. During prolonged corticotropin therapy, these patients should receive chemoprophylaxis.

Perform skin testing prior to treatment of all patients with suspected sensitivity to porcine proteins. During i.v. or immediately following i.m. or s.c. corticotropin administration, observe all patients carefully for sensitivity reactions.

There is an enhanced effect of corticotropin in patients with hypothyroidism and in those with cirrhosis.

Use the lowest possible dosage of corticotropin to control the condition under treatment, and when dosage reduction is possible, the reduction should be gradual.

Administer corticotropin for treatment only when the disease is intractable to more conventional therapy. Corticotropin should be adjunctive and not the sole therapy in the treatment of a disease.

Since maximal corticotropin stimulation of the adrenals may be limited during the first few days of treatment, administer other drugs when an immediate therapeutic effect is desirable.

When infection is present, administer appropriate anti-infective therapy during corticotropin and following discontinuation of corticotropin therapy.

Limit the treatment of acute gouty arthritis to a few days. Since rebound attacks may occur when corticotropin is discontinued, administer conventional concomitant therapy during corticotropin treatment, and for several days after it is stopped.

Psychic derangements may appear when corticotropin is used, ranging from euphoria, insomnia, mood swings, personality changes, and depression, to frank psychotic manifestations. Also, existing emotional instability or psychotic tendencies may be aggravated by corticotropin.

Use ASA cautiously in conjunction with corticotropin in hypoprothrombinemia. Administer corticotropin with caution to patients with diabetes, abscess, pyogenic infections, diverticulitis, renal insufficiency and myasthenia gravis.

Growth and development of infants and children on prolonged corticotropin therapy should be carefully observed.

Adverse Effects: Fluid and electrolyte disturbances: sodium retention, fluid retention, potassium loss, hypokalemic alkalosis, calcium loss.

Musculoskeletal: muscle weakness, steroid myopathy, loss of muscle mass, osteoporosis, vertebral compression fractures, aseptic necrosis of femoral and humeral heads, pathologic fracture of long bones.

Gastrointestinal: peptic ulcer with possible perforation and hemorrhage, pancreatitis, abdominal distention, ulcerative esophagitis.

Dermatologic: impaired wound healing, thin fragile skin, petechiae and ecchymoses, facial erythema, increased sweating, suppression of skin test reactions, acne, hyperpigmentation.

Cardiovascular: hypertension, necrotizing angiitis, congestive heart failure.

Neurological: convulsions, increased intracranial pressure with papilledema (pseudotumor cerebri) usually after treatment, headache, vertigo.

Endocrine: menstrual irregularities; development of Cushingoid state; suppression of growth in children; secondary adrenocortical and pituitary unresponsiveness, particularly in times of stress, as in trauma, surgery or illness; decreased carbohydrate tolerance; manifestations of latent diabetes mellitus; increased requirements for insulin or oral hypoglycemic agents in diabetics; hirsutism.

Ophthalmic: posterior subcapsular cataracts, increased intraocular pressure, glaucoma with possible damage to optic nerve, exophthalmos.

Metabolic: negative nitrogen balance due to protein catabolism.

Allergic reactions: especially in patients with allergic responses to proteins manifesting as dizziness, nausea and vomiting, shock, skin reactions.

Miscellaneous: abscess; prolonged ACTH administration may result in antibodies and loss of stimulatory effect.

Dosage: For deep i.m. or s.c. injection only. Standard tests for verification of adrenal responsiveness to corticotropin may utilize as much as 80 units as a single injection, or one or more injections of a lesser dosage. Perform verification tests prior to corticotropin treatment. The test should utilize the route(s) of administration proposed for treatment. Following verification, individualize dosage according to the disease under treatment and the patient's general medical condition. Determine the frequency and dose of the drug by considering disease severity, plasma and urine corticosteroid concentrations and the patient's initial response. Only gradual change in dosage schedules should be attempted, after full drug effects have become apparent.

The chronic administration of more than 40 units daily may be associated with uncontrollable adverse effects.

When dosage reduction is indicated, this should be accomplished gradually by increasing the duration between injections and/or by decreasing the quantity of corticotropin injected. During dosage reduction, carefully consider the disease being treated, the patient's general medical condition and the duration over which corticotropin was administered.

Repository corticotropin injections may be given i.m. or s.c. every 24 to 72 hours in doses of 40 to 80 units.

The usual i.m. or s.c. dose for corticotropin injection is 20 units 4 times daily.

For diagnostic purposes, corticotropin injection may be given intravenously in doses of 10 to 25 units dissolved in 500 mL of 5% glucose infused over an 8 hour period.

Suppliers: Harris (Acthar®).

Reviewed 1982.

. . . For assistance in the visual identification of drug dosage forms, refer to the PRODUCT RECOGNITION SECTION of CPS.

ACTHAR® *Harris*
ACTHAR® GEL (H.P.)

ACTH Preparations

Adrenocorticotropic Hormone

Indications: Diagnostic testing of adrenocortical function.

Corticotropin injections have limited therapeutic value in conditions responsive to corticosteroid therapy; however, corticosteroid therapy is considered to be the treatment of choice. Accordingly, corticotropin injections may be employed in the following disorders:

Rheumatic disorders: As adjunctive therapy for short term administration (to tide the patient over an acute episode or exacerbation) in psoriatic arthritis, rheumatoid arthritis, ankylosing spondylitis, acute and subacute bursitis, acute nonspecific tenosynovitis, acute gouty arthritis.

Collagen diseases: During an exacerbation or as maintenance therapy in selected cases of systemic lupus erythematosus, systemic dermatomyositis (polymyositis), acute rheumatic carditis.

Dermatologic diseases: pemphigus, bullous dermatitis herpetiformis, severe erythema multiforme (Stevens-Johnson syndrome), exfoliative dermatitis, severe psoriasis.

Allergic states: Control of severe or incapacitating allergic conditions intractable to adequate trials of conventional treatment, seasonal or perennial allergic rhinitis, bronchial asthma, contact dermatitis, atopic dermatitis, serum sickness.

Ophthalmic diseases: severe acute and chronic allergic and inflammatory processes involving the eye and its adnexa such as allergic conjunctivitis; keratitis; herpes zoster ophthalmicus, iritis, diffuse posterior uveitis and choroiditis, optic neuritis, sympathetic ophthalmia.

Respiratory diseases: symptomatic sarcoidosis, Loeffler's syndrome not manageable by other means, berylliosis.

Hematologic disorders: acquired (autoimmune) hemolytic anemia.

Neoplastic diseases: palliative management of adult leukemias and lymphomas, acute leukemia of childhood.

Edematous state: To induce a diuresis or a remission of proteinuria in the nephrotic syndrome without uremia of the idiopathic type or that due to lupus erythematosus.

Miscellaneous: tuberculous meningitis with subarachnoid block or impending block when concurrently accompanied by appropriate antituberculous chemotherapy, trichinosis of neurologic or myocardial involvement.

Contraindications: Scleroderma, osteoporosis, systemic fungal infections, ocular herpes simplex, recent surgery, history of or the presence of a peptic ulcer, congestive heart failure, hypertension, sensitivity to proteins of porcine origin.

Treatment of conditions listed within the "Indications" section when they are accompanied by primary adrenocortical insufficiency or adrenocortical hyperfunction.

Administration of i.v. corticotropin is contraindicated for treatment of conditions listed within the "Indications" section.

Precautions: Chronic corticotropin administration may lead to irreversible adverse effects. Corticotropin may only suppress symptoms and signs of chronic disease without altering the natural course of the disease. Do not administer corticotropin for treatment until adrenal responsiveness has been verified with the route of administration which will be utilized during treatment, i.m. or s.c. A rise in urinary and plasma corticosteroid values provides direct evidence of a stimulatory effect. Prolonged corticotropin administration increases the risk of hypersensitivity reactions.

Although the action of corticotropin is similar to that of exogenous adrenocortical steroids, the quantity of adrenocorticoid may be variable. In patients who receive prolonged corticotropin therapy, the additional use of rapidly acting corticosteroids before, during, and after an unusual stressful situation is indicated.

Prolonged use of corticotropin may produce posterior subcapsular cataracts and glaucoma with possible damage to the optic nerves.

Corticotropin may mask some signs of infection, and new infections including those of the eye due to fungi or viruses may appear during its use. There may be decreased resistance and inability to localize infection when corticotropin is used.

Since fetal abnormalities have been observed in experimental animals, use of corticotropin in pregnancy, nursing mothers, or women of childbearing potential requires that the potential benefits of the drug be weighed against the potential hazards to the mother and embryo or fetus. Infants born of mothers who have received substantial doses of corticotropin during pregnancy should be carefully observed for signs of hypoadrenalism and appropriate therapy instituted if such signs are present.

Corticotropin can cause elevation of blood pressure, salt and water retention and increased potassium excretion. Dietary salt restriction and potassium supplementation may be necessary. Corticotropin increases calcium excretion.

While on corticotropin therapy, do not vaccinate patients against smallpox. Undertake other immunization procedures with caution in patients who are receiving corticotropin, especially when high doses are administered because of the possible hazards of neurological complications and lack of antibody response.

Patients with latent tuberculosis or tuberculin reactivity who receive corticotropin should be closely observed as reactivation of the disease may occur. During prolonged corticotropin therapy,

these patients should receive chemoprophylaxis. Perform skin testing prior to treatment of all patients with suspected sensitivity to porcine proteins. During i.v. or immediately following i.m. or s.c. corticotropin administration, observe all patients carefully for sensitivity reactions.

There is an enhanced effect of corticotropin in patients with hypothyroidism and in those with cirrhosis.

Use lowest possible dosage of corticotropin to control the condition under treatment, and when dosage reduction is possible, the reduction should be gradual.

Administer corticotropin for treatment only when the disease is intractable to more conventional therapy. Corticotropin should be adjunctive and not the sole therapy in the treatment of a disease.

Since maximal corticotropin stimulation of the adrenals may be limited during the first few days of treatment, administer other drugs when an immediate therapeutic effect is desirable.

When infection is present, administer appropriate anti-infective therapy during corticotropin and following discontinuation of corticotropin therapy.

Limit the treatment of acute gouty arthritis to a few days. Since rebound attacks may occur when corticotropin is discontinued, administer conventional concomitant therapy during corticotropin treatment, and for several days after it is stopped.

Psychic derangements may appear when corticotropin is used, ranging from euphoria, insomnia, mood swings, personality changes, and depression, to frank psychotic manifestations. Also, existing emotional instability or psychotic tendencies may be aggravated by corticotropin.

Use ASA cautiously in conjunction with corticotropin in hypoprothrombinemia. Administer corticotropin with caution to patients with diabetes, abscess, pyogenic infections, diverticulitis, renal insufficiency and myasthenia gravis.

Growth and development of infants and children on prolonged corticotropin therapy should be carefully observed.

Adverse Effects: Fluid and electrolyte disturbances: sodium retention, fluid retention, potassium loss, hypokalemic alkalosis, calcium loss.

Musculoskeletal: muscle weakness, steroid myopathy, loss of muscle mass, osteoporosis, vertebral compression fractures, aseptic necrosis of femoral and humeral heads, pathologic fracture of long bones.

Gastrointestinal: peptic ulcer with possible perforation and hemorrhage, pancreatitis, abdominal distention, ulcerative esophagitis.

Dermatologic: impaired wound healing, thin fragile skin, petechiae and ecchymoses, facial erythema, increased sweating, suppression of skin test reactions, acne, hyperpigmentation.

Cardiovascular: hypertension, necrotizing angiitis, congestive heart failure.

Neurological: convulsions, increased intracranial pressure with papilledema, (pseudotumor cerebri) usually after treatment, headache, vertigo.

Endocrine: menstrual irregularities; development of Cushingoid state; suppression of growth in children; secondary adrenocortical and pituitary unresponsiveness, particularly in times of stress, as in trauma, surgery or illness; decreased carbohydrate tolerance; manifestations of latent diabetes mellitus; increased requirements for insulin or oral hypoglycemic agents in diabetics; hirsutism.

Ophthalmic: posterior subcapsular cataracts, increased intraocular pressure, glaucoma with possible damage to optic nerve, exophthalmos.

Metabolic: negative nitrogen balance due to protein catabolism.

Allergic reactions: especially in patients with allergic responses to proteins manifesting as dizziness, nausea and vomiting, shock, skin reactions.

Miscellaneous: abscess, prolonged ACTH may result in antibodies and loss of stimulatory effect.

Dosage: For deep i.m. or s.c. injection only. Standard tests for verification of adrenal responsiveness to corticotropin may utilize as much as 80 units as a single injection, or one or more injections of a lesser dosage. Perform verification tests prior to corticotropin treatment. The test should utilize the route(s) of administration proposed for treatment. Following verification, individualize dosage according to the disease under treatment and the patient's general medical condition. Determine the frequency and dose of the drug by considering disease severity, plasma and urine corticosteroid levels and the patient's initial response. Only gradual change in dosage schedules should be attempted, after full drug effects have become apparent.

The chronic administration of more than 40 units daily may be associated with uncontrollable adverse effects.

When dosage reduction is indicated, this should be accomplished gradually by increasing the duration between injections and/or by decreasing the quantity of corticotropin injected. During dosage reduction carefully consider the disease being treated, the patient's general medical condition and the duration over which corticotropin was administered.

Acthar Gel (H.P.), a repository corticotropin injection, is given i.m. or s.c. every 24 to 72 hours in doses of 40 to 80 units.

The usual i.m. or s.c. dose for Acthar (corticotropin injection) is 20 units 4 times daily.

For diagnostic purposes, Acthar may be given i.v. in doses of 10 to 25 units dissolved in 500 mL of 5% glucose infused over an 8 hour period.

Supplied: Acthar: Each vial of sterile, lyophilized powder contains: 25 or 40 I.U. of corticotropin and approximately 9 and 14 mg of hydrolyzed gelatin respectively.

Stable in the dry form at room temperature. Reconstitute at the time of use by dissolving in a convenient volume of Sterile Water for Injection or Sodium Chloride Injection in such a manner that the individual dose will be contained in 1 to 2 mL of solution. Refrigerate the reconstituted solution and use within 24 hours.

Acthar Gel (H.P.): Each mL contains: 40 or 80 IU of corticotropin, 16% gelatin, 0.5% phenol, not more than 0.1% cysteine (added) and Water for Injection, q.s. Available in 5 mL vials.

ACTI-B_{12} ℞ *Charton*

Hydroxocobalamin ***Hematopoietic***

Indications: In cases of anemia.

Dosage: 1 vial daily.

Supplied: Each 10 mL vial contains: 500 μg of hydroxocobalamin and certain nonmedicinal essential amino acids.

For prescribing information, refer to vitamin B_{12} monograph.

Marketed 1981

ACTIDIL® *B. W. Inc.*

Triprolidine HCl ***Antihistamine***

Indications: Seasonal hay fever, vasomotor rhinitis, spasmodic bronchial cough without dyspnea, urticaria, angioneurotic edema, serum sickness, reactions from antibiotics, itching from dermatitis, pruritus ani and vulvae, insect bites.

Contraindications: Sensitivity to triprolidine or antihistamines.

Precautions: Patients should be cautioned not to operate vehicles or hazardous machinery until their response to the drug has been determined. Since the depressant effects of antihistamines are additive to those of other drugs affecting the CNS, patients should be cautioned against drinking alcoholic beverages or taking hypnotics, sedatives, psychotherapeutic agents or other drugs with CNS depressant effects during antihistaminic therapy.

Adverse Effects: Drowsiness, dizziness, gastrointestinal disturbances and dryness of mouth are the most common untoward effects. Triprolidine may produce signs of CNS stimulation including insomnia, excitation and hyperirritability.

Dosage: Adults, 2.5 mg 2 to 3 times a day. Children over 2 years of age, 1.25 mg 2 to 3 times a day.

Supplied: Syrup: Each 5 mL of syrup contains: triprolidine HCl 1.25 mg. Available in 100 mL bottles.

Tablets: Each white tablet with code number ACTIDIL L2A on same side as diagonal score mark contains: triprolidine HCl 2.5 mg. Bottles of 100 tablets.

(Shown in Product Recognition Section)

ACTIFED® *B. W. Inc.*

Triprolidine—Pseudoephedrine
Antihistaminic—Decongestant

Indications: The prophylaxis and treatment of symptoms associated with the common cold, acute and subacute sinusitis, acute eustachian salpingitis, serous otitis media with eustachian tube congestion, aerotitis media, croup and similar lower respiratory tract diseases; in allergic conditions which respond to antihistamines, including hay fever, pollenosis, allergic and vasomotor rhinitis, allergic asthma.

Precautions: Use with caution in hypertensive patients and in patients receiving MAO inhibitors. Patients should be cautioned not to operate vehicles or hazardous machinery until their response to the drug has been determined. Since the depressant effects of antihistamines are additive to those of other drugs affecting the CNS, patients should be cautioned against drinking alcoholic beverages or taking hypnotics, sedatives, psychotherapeutic agents or other drugs with CNS depressant effects during antihistaminic therapy.

Adverse Effects: None serious. Some patients may exhibit mild sedation or mild stimulation.

Overdose: Symptoms: Insomnia, tremors, tachycardia.
Treatment: There is no specific antidote for triprolidine or pseudoephedrine. General measures to eliminate the drug and reduce its absorption should be undertaken. If respiratory depression is severe, intubation and artificial respiration should be used. Convulsions should be treated with diazepam or paraldehyde. Maintain blood pressure through fluid replacement and supportive measures.

Dosage: Adult dose, 10 mL of syrup or 1 tablet 3 times daily. Children up to 6 years of age, ½ adult dose. Infants up to 4 months, 2.5 mL of syrup 3 times daily.

Supplied: Syrup, Tablets: Each white, biconvex tablet with code number ACTIFED M2A on same side as diagonal score mark or each 10 mL of clear, lemon yellow, unflavored and almost odorless syrup contains: triprolidine HCl 2.5 mg and pseudoephedrine HCl 60 mg. Syrup contains tartrazine.

The syrup is available in 100 and 250 mL bottles; tablets are available in packages of 12 and 24 tablets, bottles of 100 and 500 tablets.

(Shown in Product Recognition Section)

Reviewed 1982

ACTIFED®-A *B. W. Inc.*

Triprolidine—Pseudoephedrine Compound
Decongestant—Antihistaminic—Analgesic

Pharmacology: Actifed-A combines the antihistaminic action of triprolidine HCl and the decongestant effect of pseudoephedrine HCl with the analgesic and antipyretic activity of acetaminophen.

Indications: For the symptomatic relief of congestion, aches, pain and fever associated with colds and sinusitis.

Precautions and Adverse Effects: See Actifed and acetaminophen monographs.

Dosage: Dosages indicated may be given 3 times daily.

Adults and children over 14 years: 1 tablet; children 10 years to 14 years: ½ tablet. Not recommended for children under 10 years of age.

Tablets: Each white uncoated tablet, flat face, scored same side as code number WELLCOME A2B contains: triprolidine HCl 2.5 mg, pseudoephedrine HCl 60 mg, acetaminophen 300 mg. Available in cartons of 18 tablets and bottles of 50 tablets.

(Shown in Product Recognition Section)

ACTIFED® DM *B.W. Inc.*

Triprolidine — Pseudoephedrine — Dextromethorphan
Antihistaminic — Decongestant — Antitussive

Indications: The prophylaxis and treatment of allergic conditions in which antihistamines have been found useful, such as: hay fever, pollenosis, urticaria, allergic asthma, allergic rhinitis, and vasomotor rhinitis; the prophylaxis and treatment of the symptoms associated with the common cold, acute and subacute sinusitis, acute eustachian salpingitis, serous otitis media with eustachian tube congestion, aerotitis media, croup, and similar lower respiratory tract diseases.

Contraindications: Sensitivity to triprolidine, pseudoephedrine or dextromethorphan. Should not be administered to patients receiving MAO inhibitors.

Precautions: Use with caution in hypertensive patients. Patients should be cautioned not to operate vehicles or hazardous machinery until their response to the drug has been determined. Since the depressant effects of antihistamines are additive to those of other drugs affecting the CNS, patients should be cautioned against drinking alcoholic beverages or taking hypnotics, sedatives, psychotherapeutic agents or other drugs with CNS depressant effects during antihistaminic therapy.

Adverse Effects: Mild stimulation, nausea or mild sedation has been seen in a few patients.

Overdose: Symptoms: The clinical picture of acute poisoning would probably be characterized by the toxic effects of triprolidine and/or pseudoephedrine. Mild stimulation, nausea, or mild sedation has been seen in a few patients. In severe cases, there may be respiratory depression due to the dextromethorphan component.

Treatment: There is no specific antidote for triprolidine or pseudoephedrine. General measures to eliminate the drug and reduce its absorption should be undertaken. In severe cases of acute poisoning, where the respiratory depressive effects of dextromethorphan may be apparent, the following may be indicated: levallorphan: Adults: 1.5 to 2 mg i.v.; Children: 0.5 to 1 mg i.v.; or nalorphine: Adults: 5 to 10 mg i.v.; Children: 2.5 to 5 mg i.v. (Depending on the patient's response, the dose can be repeated if necessary, at intervals of 20 to 30 minutes); or naloxone: Adults: 400 μg s.c. Children: 5 to 10 μg/kg s.c. Depending on the patient's response, the dose can be repeated at 2 to 3 minute intervals.

Dosage: Adults and children over 12 years, 10 mL 3 times daily. Children: aged 2 to 6 years: 2.5 mL 3 times daily; aged 6 to 12 years: 5 mL 3 times daily.

Supplied: Each 5 mL contains: 1.25 mg triprolidine hydrochloride, 30 mg pseudoephedrine hydrochloride and 15 mg dextromethorphan. Bottles of 100 and 250 mL.

Reviewed 1982

ACTIFED®-PLUS *B. W. Inc.*

Triprolidine—Pseudoephedrine Compound
Antitussive—Decongestant —Antihistaminic

Indications: For the temporary relief of cough and nasal congestion associated with the common cold, nasal allergies and postnasal drip.

Precautions: As for Actifed.

Adverse Effects: A few patients may exhibit mild stimulation, nausea or mild sedation.

Overdose: Treatment: As for Actifed. Also gastric lavage, caffeine.

Dosage: Dosages indicated below may be given 3 times daily.

	TABLETS		SYRUP
Children over 12 years and adults	1	or	10 mL
Children 6 years to 12 years	½	or	5 mL
Infants and children up to 6 years	—		2.5 mL

Supplied: Syrup: Each 5 mL of cherry-red syrup with slightly acidic taste contains: noscapine 15 mg, pseudoephedrine HCl 30 mg, triprolidine HCl 2 mg. Contains 5 mL of ethyl alcohol B.P./100 mL. Contains tartrazine. Available in 100 and 250 mL bottles.

Tablets: Each pink, biconvex press coated tablet, with code number WELLCOME B7B on same side as diagonal score mark contains: noscapine 30 mg, triprolidine HCl 2.5 mg, pseudoephedrine HCl 60 mg. When cut in half the tablet reveals a white core. Available in cartons of 18 tablets and bottles of 50 tablets.

(Shown in Product Recognition Section)

ACTINAC® Ⓟ *Roussel*

Chloramphenicol—Hydrocortisone Compound

Acne Therapy

Indications: Topical treatment of acne vulgaris where treatment with a topical corticosteroid is considered appropriate. Therapy has been associated with a reduction in papules, pustules and the accompanying inflammation and erythema. Efficacy in treating the comedone and cyst components of acne has not been established.

Contraindications: Tuberculosis of the skin, viral infections including herpes simplex, vaccinia or varicella, acute fungal or yeast infections. Sensitivity to any of the product's components.

Precautions: Keep away from the eyes and mouth.

Discontinue use temporarily if excessive drying, irritation, or scaling occurs.

Although untoward effects associated with the use of topical corticosteroids are uncommon and not to be expected from ordinary use, sensitization and irritation have been noted in rare instances. Application to extensive areas, too frequent application, or application under occlusive dressings may result in systemic absorption with symptoms of adrenal suppression, localized atrophy and striae.

If secondary bacterial infection exists, other appropriate antibacterial therapy may also be initiated; however, if overgrowth develops, discontinue therapy.

Interim assessments of the patient's progress should be made at not less than 2 week intervals. Treatment should be discontinued after maximum benefit has been obtained and reinstituted only if a relapse occurs. If no significant improvement in the condition is observed within 4 to 6 weeks, discontinue treatment.

Adverse Effects: Following topical administration of chloramphenicol preparations, signs of local irritation with subjective symptoms of itchng or burning, angioneurotic edema, urticaria, vesicular and maculopapular dermatitis have been reported in patients sensitive to chloramphenicol and are cause for discontinuing the medication.

The typical adverse reactions of topical corticosteroids (see Precautions) might be expected with prolonged use, although the frequency of their occurrence with hydrocortisone is less than with fluorinated corticosteroids and they have not been reported with Actinac.

Reported adverse reactions include: excessive drying of the skin, erythema, contact dermatitis, eye irritation, a burning sensation and facial flushing. Drying of the skin and erythema have also been noted following use of a vehicle control from which hydrocortisone and chloramphenicol were omitted.

Overdose: Symptoms: Excessive drying and erythema or burning and irritation of the skin, appearance of fungal or bacterial overgrowth and localized atrophy or striae formation are all possible symptoms of overdosage.

Treatment: If overdosage is suspected, stop treatment. Similarly, discontinue therapy and initiate appropriate therapy in the event of fungal or bacterial overgrowth. A bland ointment may be used to alleviate dryness and itching.

In case of accidental ingestion of lotion by children the amount swallowed would be expected to be minimal. Symptoms would probably consist of mild gastrointestinal disturbances. The chloramphenicol content of a single vial of powder is 200 mg and therefore would not likely prove dangerous if ingested. In the event of a severe reaction, treatment consists of general measures such as the induction of emesis, gastric lavage, catharsis and the forcing of fluids.

Dosage: Wash the affected area with soap and water, then apply the reconstituted lotion with cotton wool or gauze morning and night for the first 4 days and then only at night thereafter.

Supplied: Available as a single pack of 2 bottles each containing 5 g of powder and 2 bottles each containing 16 mL of aqueous vehicle. Store in a cool place. Avoid excessive heat.

The reconstituted lotion, prepared by mixing the contents of one bottle of powder with one bottle of aqueous vehicle, is stable at room temperature for 21 days.

Each g of powder contains: chloramphenicol B.P. 40 mg, hydrocortisone acetate B.P. 40 mg, butoxyethyl nicotinate 24 mg, allantoin 24 mg, precipitated sulphur B.P. 320 mg, excipient q.s.

ADAPETTES® *Alcon-bp*

Contact Lens Solution

Indications: A cleaning and rewetting solution for use with the contact lens (hard or soft) on the eye.

Method of Use: Place a drop of solution on each lens and blink 2 or 3 times. If discomfort persists, remove lenses.

Supplied: Each 15 mL dropper vial contains: a sterile, buffered, isotonic solution of polyvinylpyrrolidone 1.67%, other water soluble polymers and thimerosal not exceeding 0.004% and edetate disodium 0.1% as preservatives.

ADAPT® *Alcon-bp*

Hard Contact Lens Solution

Indications: A cushioning solution for hard contact lenses.

Method of Use: Instill 1 drop of solution directly into each eye prior to lens insertion or place 1 drop on the concave surface of the lens, shake off excess and insert lens. Do not rub solution on lens.

Supplied: Each 15 mL dropper vial contains: a sterile, buffered, isotonic solution of polyvinylpyrrolidone 1.67%, other water soluble polymers, hydroxyethylcellulose 0.55% with thimerosal not exceeding 0.004% and edetate disodium 0.1% as preservatives.

ADASEPT Acne Gel *Odan*

Salicylic Acid—Thiosulfate Compound

Acne Therapy

Supplied: Each 50 mL plastic applicator bottle contains: triclosan 0.5%, salicylic acid 2% and sodium thiosulfate 8% in a colorless gel base.

ADASEPT Cleanser *Odan*

Triclosan ***Antibacterial Skin Cleanser***

Supplied: Each 120, 250 and 455 mL plastic applicator bottle contains: triclosan 0.5% in a blend of amphoteric and anionic surfactants and propylene glycol. Acid pH.

ADDAMEL *Pharmacia*

Electrolyte and Trace Element Supplement

Indications: Addamel, when added to Vamin, is intended to meet average basal requirements of electrolytes and trace elements during parenteral nutrition of adults.

The average daily requirements of Ca, Mg, Fe, Zn, Mn, Cu, F, I, and Cl are supplied in Addamel. In addition, Vamin supplies 50 mEq of sodium and 20 mEq of potassium/litre. In conditions with excessive losses of electrolytes and trace elements, greater quantities of certain individual elements, especially potassium and phosphate, may be required.

Precautions: During parenteral nutrition, the serum levels of electrolytes should be monitored and controlled at regular intervals. When additional quantities of any single element are required, that element should be added separately from a single source. To avoid overdose, the amount of Addamel should not be increased in order to meet increased requirements for a single element.

Not for pediatric use.

Use in Pregnancy: As far as is presently known, Addamel can be used safely during pregnancy.

Dosage: Addamel must be diluted before use. Do not mix with other drugs due to the risk of precipitation.

Add one vial (10 mL) of Addamel aseptically to 500 to 1000 mL of Vamin.

Supplied: Each 10 mL vial of sterile solution contains: Calcium 200 mg (10 mEq; 5 mmol), Magnesium 36 mg (3 mEq; 1.5 mmol), Iron 2.8 mg (0.15 mEq; 50 μmol), Zinc 1.3 mg (0.04 mEq; 20 μmol), Manganese 2.2 mg (0.08 mEq; 40 μmol), Copper 0.3 mg (0.01 mEq; 5 μmol), Fluorine 0.95 mg (0.05 mEq; 0.05 mmol), Iodine 0.13 mg (1 μEq; 1 μmol), Chlorine 470 mg (13.3 mEq; 13.3 mmol).

Available in cartons of 5 x 10 mL vials. Store at room temperature.

Marketed 1981

ADEFLOR® *Upjohn*

Fluoride—Vitamins ***Prenatal Supplement***

Indications: Aids in the prevention of dental caries and the prophylaxis of vitamin deficiencies.

Dietary supplement of vitamins, minerals and fluoride during pregnancy.

Contraindications: Hemochromatosis, hemosiderosis, hemolytic anemia.

Precautions: The recommended dosage should not be exceeded, since an excessive intake of fluoride may result in dental fluorosis. Should be used only in areas where the fluoride content of drinking water is 1 p.p.m. or less, and when the total water intake is such that fluoride ingestion from this source does not exceed 500 μg daily. As with all medications, this preparation should be kept out of reach of children.

Neurologic involvement may develop or progress, despite temporary remission of anemia, in patients with pernicious anemia who receive more than 100 μg of folic acid per day and who are inadequately treated with vitamin B_{12}. Periodic examinations and laboratory studies of pernicious anemia patients are essential.

Oral iron preparations may aggravate existing peptic ulcer, regional enteritis and ulcerative colitis.

Iron compounds taken orally can impair the absorption of tetracycline antibiotics. Antacids given concomitantly with iron compounds decrease iron absorption.

Adverse Effects: Rarely, in iron sensitive patients, mild gastrointestinal upsets may occur.

Eczema, atopic dermatitis, and urticaria have been occasionally associated with ingestion of fluoride.

Dosage: 1 tablet daily.

Supplied: Prenatal Tablets: Each pink, coated, oval tablet branded Upjohn contains: vitamin A 6,000 I.U., vitamin D 400 I.U., thiamine (as the mononitrate) 1.2 mg, riboflavin 2.5 mg, ascorbic acid (as sodium ascorbate) 100 mg, niacinamide 20 mg, pyridoxine HCl 10 mg, d-pantothenic acid (as calcium d-pantothenate) 9.2 mg, vitamin B_{12} 2 μg, folic acid 400 μg, (0.4 mg) fluoride (as sodium fluoride) 1 mg, calcium (as carbonate) 250 mg, elemental iron (as ferrous fumarate) 30 mg. Sodium content: 18 mg/tablet. Bottles of 60 and 500 tablets.

(Shown in Product Recognition Section)

ADRENALIN® *P.D.*

Epinephrine HCl ***Sympathomimetic***

Supplied: 1:1,000 Aqueous Solution: Each mL contains: epinephrine HCl 1 mg dissolved in isotonic sodium chloride solution. Available in 30 mL Steri-Vials, 1 mL ampuls in boxes of 10; 1 oz. screw-capped bottles for topical use.

For prescribing information, refer to epinephrine monograph.

ADRENOMYXIN® Ⓟ *Sands*

Neomycin—Polymyxin—Hydrocortisone

Antibiotic—Corticosteroid

Indications: Topical application is indicated in the following conditions when threatened with or complicated by infection due to neomycin sensitive organisms: Eye: phlyctenular keratoconjunctivitis, nonspecific superficial keratitis, acne rosacea keratitis, purulent conjunctivitis, postoperative keratitis, sclerokeratitis, episcleritis, traumatic keratitis, blepharitis, anterior uveitis.

External ear canal: seborrheic dermatitis, contact dermatitis, infected eczematoid dermatitis, draining otitis media (as an adjunct to antibiotic therapy).

Contraindications: Hypersensitivity to any of the components. Viral diseases of the cornea and conjunctiva; tuberculosis of the eye; fungal infections of the eye; acute purulent untreated infections of the eye which, like other diseases caused by microorganisms, may be masked or enhanced by the presence of the steroid.

Precautions: The sterility of the product may not persist after the bottle has been opened. Patients should be instructed to take appropriate measures to avoid contamination, especially when applying the preparation to open lesions of the eye.

If signs of irritation or sensitivity develop, application should be discontinued. According to current medical literature there has been an increase in the prevalence of neomycin hypersensitivity.

The safety of the use of topical steroid preparations during pregnancy has not been fully established. Therefore, steroids should not be used unnecessarily during pregnancy or for prolonged periods of time. The prolonged use of antibiotic containing preparations may result in overgrowth of nonsusceptible organisms, particularly fungi. If new infections appear during treatment, appropriate therapy should be instituted; and if such is not available, as in the case of herpes simplex keratitis, all products containing steroids should be discontinued.

Adverse Effects: Extended ophthalmic use of corticosteroid drugs may cause increased intra-ocular pressure in certain individuals and in those diseases causing thinning of the cornea, perforation has been known to occur. Systemic adverse effects may occur with extensive use of topical steroids. Preparations should be used with caution in the presence of perforated eardrums and long-standing otitis media.

Dosage: Eyes: 1 or 2 drops in eye every 3 or 4 hours, more frequently in acute conditions if required.

Ears: 3 or 4 drops in ear 3 or 4 times daily or more frequently as required.

Supplied: Each mL of sterile ophthalmic/otic suspension contains: polymyxin B sulfate 10,000 units, neomycin sulfate 5 mg, hydrocortisone 10 mg (1%). Available in 7 mL plastic dropper bottles.