drug facts and comparisons®

1990 edition

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Drug Facts and Comparisons,® 1990 Edition

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Preface

Facts and Comparisons® provides a broad range of drug information to fulfill the everyday needs of practicing health care professionals. Developed in 1945 by pharmacist Erwin K. Kastrup, *Facts and Comparisons* was designed to provide objective information in a format to facilitate comparisons of drug products. Although the basic concepts remain the same, the content of *Facts* continues to evolve to reflect the changing information needs of health care professionals.

Facts and Comparisons, a loose-leaf text, is kept up-to-date through the issue of monthly updates. In 1977, the Microfiche Edition was introduced to provide the same monthly updated information in a microfilm format. The Annual Bound Edition of *Facts and Comparisons* was first published in 1978. In 1982, the title became *Drug Facts and Comparisons* which better describes the nature of the reference.

The continuous introduction of new drugs and products emphasizes the need for current information. In the past year, much of the text has been significantly revised. Hundreds of new drug products, dosage forms and formula changes are included. This edition incorporates 30 new drugs: Apraclonidine *(Iodipine),* astemizole *(Hismanal),* bupropion *(Wellbutrin),* carboplatin *(Paraplatin),* carteolol *(Cartrol),* cefixime *(Suprax),* difenoxin *(Motofen),* epoetin alfa *(Epogen),* ethanolamine oleate *(Ethamolin),* flurbiprofen, oral *(Ansaid),* flutamide *(Eulexin),* ganciclovir *(Cytovene),* ifosfamide *(Ifex),* mesna *(Mesnex),* metronidazole, topical *(MetroGel),* minoxidil, topical *(Rogaine),* misoprostol *(Cytotec),* nicardipine *(Cardene),* nimodipine *(Nimotop),* octreotide *(Sandostatin),* oxiconazole *(Oxistat),* penbutolol *(Levatol),* pentamidine isethionate, aerosol *(NebuPent),* pergolide *(Permax),* selegiline *(Eldepryl),* sodium benzoate/sodium phenylacetate *(Ucephan),* sulconazole *(Exelderm),* suprofen, ophthalmic *(Profenal),* tiopronin *(Thiola),* and ursodiol *(Actigall).*

Sections which have undergone major revisions include cardiac glycosides, vasopressors used in shock, ACE inhibitors, β-adrenergic blockers, calcium channel blockers, antihypertensives, antihyperlipidemics, respiratory products, nasal decongestants, antihistamines, salicylates, NSAIDs, antiemetics/antivertigo agents, antacids, H_2 antagonists, anticholinergics, ophthalmics, psoralens, IV and enteral nutrients, fluoroquinolones, and influenza vaccine 1989-90. Also, more than 45 tables and diagrams have been added or extensively revised. A new section this year is the pharmaceutical manufacturer index.

Our investigational drug section in chapter 12 has been expanded. New investigational drugs in this edition include: Adenosine, clomipramine, clozapine, dilevalol, doxazosin, indecainide, isradipine, moricizine, rimantidine and tolrestat.

As this edition goes to press, we begin the process of revision for the 1991 edition. As always, *Facts and Comparisons* remains dedicated to fulfilling the drug information needs of health care professionals. Comments, criticisms and suggestions are always welcome.

B.R.O.

Introduction

Drug Facts and Comparisons is a comprehensive drug information compendium. Organized by therapeutic drug classes, the unique format is designed to provide a wide scope of drug information in a manner which facilitates comparisons among drugs. A comprehensive index, a detailed table of contents for each chapter and extensive cross referencing enable the reader to quickly locate needed information. The following pages explain the organization and contents of *Drug Facts and Comparisons* in detail. All readers are urged to review this information to assure efficient and effective use of *Drug Facts and Comparisons.*

Editorial Policy:

The core of information for monographs in *Drug Facts and Comparisons* is based on the most current FDA approved package literature. Information is edited and presented in a standardized format to provide a more convenient and meaningful form for the subscriber. FDA approved indications and dosage recommendations are included. In addition, other established or potential uses are discussed and are designated as *"Unlabeled Uses"*. Information in the monographs (actions, drug interactions, etc.) is frequently supplemented by current data obtained from the biomedical literature. All information which is not included in approved package literature is thoroughly documented, reviewed and evaluated by the editorial staff.

Most of the products listed are protected by letters of patent and their names are trademarked and registered by the firm whose name appears with the product. Identification of the product distributor is given in parentheses next to the brand name. The distributor may or may not be the actual manufacturer or fabricator of the final dosage form. Listing of specific products is an indication only of availability on the market and does not constitute an endorsement or recommendation.

Products which contain identical amounts of active ingredients are listed together for comparison as an aid in product selection. Drug product interchange is regulated by state laws; listing of products together does not imply that they are therapeutically equivalent or legally interchangeable. Caution is particularly advised when comparing sustained release, timed release or repeat action dosage forms.

Editorial Panel:

The editorial panel includes recognized experts in the fields of clinical pharmacology, therapeutics and drug information. Panelists review monographs and provide direction for the revision of *Drug Facts and Comparisons.* In addition to the editorial panel, other authorities with specific expertise are consulted as necessary.

Organization:

Information in *Drug Facts and Comparisons* is organized by therapeutic use. Each of the twelve chapters is divided into groups and subgroups to facilitate comparisons of drugs and drug products with similar uses. The first page of each chapter provides a detailed outline, including page references, of the information presented in that chapter.

Products most similar in content or use are listed together. This format of presenting the FACTS makes it easy to make COMPARISONS of identical, similar or related products. Because drugs are listed by use, some drugs with multiple uses may be listed in more than one section of the book.

Index:

The alphabetical index includes page references for all drugs by their generic name, brand name, synonyms, common abbreviations, and therapeutic group names. Drug products recently withdrawn from the market that are listed in the book for reference purposes are included in the index with the designation (W).

Drug Monographs:

Prescribing information is presented in comprehensive drug monographs. General information on a group of closely related drugs (eg, Thiazide Diuretics) may be presented in a group monograph. Specific information relating to a particular drug is presented in an individual monograph under the generic name of the drug. All monographs are divided into sections identified with bold titles for ease in locating the desired information.

Actions: This section gives a brief summary of the known pharmacologic and pharmacokinetic properties.

Indications: All indications or uses listed are FDA approved unless specifically designated as *"Unlabeled Uses"*.

Contraindications: This section specifies those conditions in which the drug should NOT be used.

Warnings and Precautions: These sections list conditions in which use of the drug may be hazardous, precautions to observe and parameters to monitor during therapy.

Drug Interactions: A brief summary of documented, clinically significant drug-drug, drug-food and drug-lab test interactions is provided.

Adverse Reactions: Reported adverse reactions are presented. Incidence data on adverse effects are included when available.

Overdosage: The clinical manifestations of toxicity and treatment of overdosage are given for most agents.

Patient Information: Essential information required by the patient for safe and effective self-administration of the medication is included.

Administration and Dosage: Dosage ranges and methods of administration are presented.

Product Listings:
Individual products are listed following each monograph. The format and components of the product listings are discussed below and illustrated on the opposite page.

1. Cross references to the appropriate drug monograph(s) for complete prescribing information appear at the top of the page.
2. Products are grouped by dosage form or strength.
3. Identical brand name products are listed in alphabetical order.
4. The name of the distributor is given in parentheses next to the product name.
5. Products available by their generic name from multiple sources are indicated as available from (Various) distributors.
6. Package sizes are given for all dosage forms and strengths of each product.
7. Product identification imprint codes are indicated by the symbol #.
8. Distribution status of products is indicated as *Rx* or *otc*.
9. Controlled substances are designated by their schedule (*c-II*, *c-III*, *c-IV*, or *c-V*).
10. Sugar free liquid preparations are designated by *sf*.
11. Combination products are listed in tables to facilitate comparisons. Products most similar in formulation are listed next to each other.
12. Products with identical formulations are listed together.
13. The Cost Index, located on the right side of the product listings, is designed to give an indication of the relative cost of similar or identical products. It's simply a ratio of the average wholesale prices for equivalent quantities of a drug. The Cost Indices for dosage forms of different strengths are adjusted to accurately compare equivalent amounts of products. The basis for the Cost Index calculation is given at the bottom of each table of product listings.

    As an example of the Cost Index, if product A has a Cost Index of 45, and product B has a Cost Index of 15, product A is 3 times as expensive as product B (based on average wholesale cost).

    The Cost Index is only an indication of *relative wholesale costs.* The Cost Index is NOT a rating or recommendation. It is based only on average wholesale price and is presented for informational purposes only, without consideration of potential differences in the quality of similar products.

1 Complete prescribing information for these products begins on page 328.

Penicillinase-Resistant Penicillins (Cont.)

CLOXACILLIN SODIUM

Indications:

The treatment of infections due to penicillinase-producing staphylococci. They may be used to initiate therapy in any patient in whom a staphylococcal infection is suspected. (See page 328c concerning use of penicillinase-resistant penicillins.)

Administration and Dosage:

Mild to moderate upper respiratory and localized skin and soft tissue infections:
Adults and children over 20 kg – 250 mg every 6 hours.
Children less than 20 kg – 50 mg/kg/day in equally divided doses every 6 hours.
Severe infections (lower respiratory tract or disseminated infections):
Adults and children over 20 kg – 500 mg to 1 g every 6 hours.
Children less than 20 kg – 100 mg/kg/day or more in equal doses every 6 hours.

				C.I.*
Rx	**Cloxacillin Sodium** (Various) 5	**Capsules:** 250 mg 2	In 100s.	46+
Rx	**Cloxapen** (Beecham Labs)		(#BMP 169). Green/beige. In 100s. 6	71
Rx	**Tegopen** (Bristol)		(#Bristol 7935). In 100s.	150
Rx	**Cloxacillin Sodium** (Various)	**Capsules:** 500 mg	In 100s.	37+
Rx	**Cloxapen** (Beecham Labs) 4		(#BMP 170). Green/beige. In 100s. 7	71
Rx	**Tegopen** (Bristol)		(#Bristol 7496). In 100s.	149
Rx	**Cloxacillin Sodium** (Various) 8	**Powder for Oral Solution:** 125 mg per 5 ml when reconstituted	In 100 and 200 ml.	57+
Rx	**Tegopen** (Bristol)		Saccharin. In 100 & 200 ml.	214

* Cost Index based on cost per 500 mg. # Product identification code.

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COUGH PREPARATIONS (Cont.)

Refer to the general discussion of these products beginning on page 199.
Content given per 5 ml.

Antitussive Combinations, Liquids (Con

	Product & Distributor	Decongestant	Antihistamine	Antitussive	
otc *sf* 10	**Colrex Cough Syrup** (Reid-Rowell)	5 mg phenylephrine HCl	2 mg chlorphenir-amine maleate	10 mg dextromethor-phan HBr	4.5
otc *sf*	**Codimal DM Syrup** (Central)	5 mg phenylephrine HCl	8.33 mg pyrilamine maleate	10 mg dextromethor-phan HBr	4% Sa
otc 3	**Myminicol Liquid** (My-K Labs)	12.5 mg phenylpro-panolamine HCl	2 mg chlorphenir-amine maleate	10 mg dextromethor-phan HBr	
otc 3	**Pertussin AM Liquid** (Canaan Labs)				9.5 So
otc 3	**Threamine DM Syrup** (Various)				
otc 11	**Triaminicol Multi-Symptom Cold Syrup** (Sandoz)				
otc 12	**Tricodene Forte Liquid** (Pfeiffer)				
otc 12	**Triminol Cough Syrup** (Rugby)				
otc *sf* 11	**Trind DM Liquid** (Mead Johnson Nutritional)	12.5 mg phenylpro-panolamine HCl	2 mg chlorphenir-amine maleate	7.5 mg dextromethor-phan HBr	5% So
otc 11	**Cheracol Plus Liquid** (Upjohn)	8.3 mg phenylpro-panolamine HCl	1.3 mg chlorphenir-amine maleate	6.7 mg dextromethor-phan HBr	8% So
otc 11	**Halls Mentho-Lyptus Decongestant Liquid** (Warner-Lambert)	18.75 mg phenylpro-panolamine HCl		7.5 mg dextromethor-phan HBr	7 m 6.3 22
c-v 9	**Tricodene Syrup** (Pfeiffer)		4.17 mg pyrilamine maleate	8.1 mg codeine phosphate	Te m

* Cost Index based on cost per 5 ml. *sf* – Sugar free.

(Continued on following page)

Table of Contents

Note: A detailed table of contents appears on the first page of each chapter.

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nutritional products

Chapter 7

Nutritional products

Recommended Dietary Allowances (RDA) are published by the Food and Nutrition Board, National Research Council-National Academy of Sciences, as a guide for nutritional problems and to provide standards of good nutrition for different age groups. They are revised periodically.

The RDA values are *not requirements;* they are *recommended* daily intakes of certain essential nutrients. Based on available scientific knowledge, they are believed to be adequate for known nutritional needs for most *healthy* persons under usual environmental stresses. The recommended allowances vary for age and sex, with extra allowances for women during pregnancy and lactation. The most commonly used RDA values (the "reference male" and "reference female") are those of adults 23 to 50 years of age. With the exception of energy (kilocalories), the RDA provide for individual requirement variations and prevent symptoms of clinical deficiency of 97% of the population.

RDA have been established for 10 of the 13 known essential nutrients; present knowledge of human nutritional needs of vitamin K, pantothenic acid and biotin is incomplete. Therefore, to ensure adequate nutrient intake, obtain the recommended allowances from as varied a selection of foods as possible. Nutritionists suggest that dietary planning include regular intake of each of the four basic food groups:

1. Milk, cheese, dairy products – Minimum 2 servings/day.
2. Meat, poultry, fish, beans – Minimum 2 servings/day.
3. Vegetables, fruit – Minimum 4 servings/day.
4. Bread, cereal (whole-grain and enriched or fortified) – Minimum 4 servings/day.

Such a balance, in sufficient quantities will provide about 1200 kcal, enough protein, and most of the vitamins and minerals required daily. A person may increase nutrient and energy intake by consuming larger quantities (or more servings/day) of the four basic food groups. Nutrient and energy intake may also be increased by selecting food from the fifth group, fats-sweets-alcohol, which provides mainly energy.

RDA quantities apply only to healthy persons and are not intended to cover therapeutic nutritional requirements in disease or other abnormal states (ie, metabolic disorders, weight reduction, chronic disease, drug therapy). Although certain single nutrients in larger quantities may have pharmacologic actions, these are unrelated to nutritional functions. There is no convincing evidence that consuming excessive quantities of single nutrients will cure or prevent nonnutritional diseases.

The "official" listings of United States Recommended Daily Allowances (US-RDAs) should not be confused with the RDA values. US-RDA are derived from the 1968 RDA and serve as legal standards for nutritional labeling of food and dietary food and dietary supplement products controlled by the Food and Drug Administration. Generally, they represent the higher value of the male or female RDA and are grouped into only three age brackets plus one category for pregnant or lactating women. Prior to 1972, these allowances were erroneously listed as minimum daily requirements (MDR). A second fallacy perpetuated by US-RDA labeling of foods is the implication that a food is defective if it does not contain all the officially established nutrients in their full US-RDA quantities. No individual food is nutritionally complete, but several foods together should complement each other to provide maximal nutrient balance and to minimize naturally occurring toxic principles consumed from any individual foodstuff.

The Recommended Dietary Allowances (RDA) for adult males and adult females are included in each individual vitamin monograph. The table on the following page presents the listing of vitamin and mineral RDA values for all age groups as published in *Recommended Dietary Allowances,* 9th Edition, National Academy of Sciences, Washington, D.C., 1980.