DRUG FACTS AND COMPARISONS®

2011

Wolters Kluwer Health | Facts & Comparisons®

YOUR ANSWER FOR DRUG ANSWERS

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Wolters Kluwer Health
77 Westport Plaza, Suite 450
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Phone 314-216-2100 • 800-223-0554
Fax 314-878-5563
factsandcomparisons.com

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Louisville, Kentucky

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Foreword

Facts & Comparisons™, a part of Wolters Kluwer Health, has served the drug information needs of pharmacists and other health care professionals since its inception in 1946 by providing timely, accurate, comprehensive, unbiased, comparative information on prescription and nonprescription medications. *Drug Facts and Comparisons® (DFC),* our flagship product, is the primary source of drug information and the reference of choice for our many loyal subscribers because of its uncompromising editorial quality, reliability, and ease of use. *DFC* has remained unique among other drug information resources because of its organization by therapeutic use, providing single drug monographs with complete prescribing information as well as in-depth comparisons of closely related agents. Over the years, *DFC* has changed in size and scope, but the concept has never changed. That is why health care professionals continue to look to Facts & Comparisons™ to keep them abreast of important information in their practice.

In addition to the annual bound edition, *DFC* is also available as the popular monthly updated loose-leaf publication and as an annual pocket-size softbound abridged version. These versions allow customers to choose the format that is best suited to their practice site and workflow.

Customers who prefer the speed and efficiency of electronic products can access *DFC* through *Facts & Comparisons® eAnswers,* our electronic library of reference information, which is available on-line or CD ROM. In addition to *DFC,* other content sets available on *Facts & Comparisons® eAnswers* include *Drug Interaction Facts, A to Z Drug Facts, Nonprescription Drug Therapy, Off-Label Drug Facts, Med Facts* (patient drug information handouts), *Review of Natural Products, Cancer Chemotherapy,* and *Drug Identifier.* Information about *Facts & Comparisons® eAnswers,* can be accessed through www.factsandcomparisons.com. Facts & Comparisons™ also offers drug information for handheld personal data assistants, available for downloading at www.factsandcomparisons.com.

Drug Facts and Comparisons™ monographs are also integrated into Medi-Span's Drug Information Bridge, a pre-programmed application programming interface (API) that includes Medi-Span's drug files and clinical databases. The integration of the *DFC* referential content with Medi-Span's premier databases provides superior point-of-care solutions for our professional customers.

Facts & Comparisons™ takes our mission of providing drug information to health care professionals very seriously, which is why we continue to invest in technology, improve our current publications, and stay in contact with our customers to make sure we maintain the high standards we set many years ago when Erwin Kastrup, RPh, first developed this concept. We have many people to thank for helping us achieve these goals, including our Editorial Advisory Panel, reviewers, contributors, and our excellent, dedicated employees, but more than anything we want to thank our loyal subscribers who have helped us develop and improve our drug information publications that are so widely used today.

We are dedicated to maintaining the traditions that are important to both Facts & Comparisons™ and our customers, but we are also dedicated to evolving our products to meet the changing technologies and the changing needs of health care professionals. These goals only can be accomplished by responding to the comments and suggestions from our subscribers, which we encourage and appreciate. As always, let us know how we can better serve you and your drug information needs.

Cathy H. Reilly
Vice President and Publisher

Preface

As the premier publisher of drug information, Facts & Comparisons™ provides a broad range of print and electronic resources to fulfill the day-to-day needs of practicing health care professionals. *Drug Facts and Comparisons® (DFC)*, our flagship publication developed in 1946 by pharmacist Erwin K. Kastrup, was initially designed to provide objective information in a format that facilitated unbiased comparisons of drug products in a timely manner. After more than 60 years, the basic concepts remain the same. However, the content and presentation of material in *DFC* continues to evolve to reflect the changing needs of the health care environment.

The annual bound edition is one of several formats in which *DFC* is available. The original loose-leaf version is kept up to date through monthly print updates. An electronic version, updated continously, is available as part of *Facts & Comparisons® eAnswers* and can be accessed via www.factsandcomparisons.com.

Facts & Comparisons® eAnswers also provides full monographs with complete prescribing information for nearly every single agent drug product, while the print versions continue to present abbreviated drug monographs in instances where a class monograph exists.

The new 65th edition of *DFC* incorporates 31 new drugs: artemether/lumefantrine (*Coartem* by Novartis), asenaprine (*Saphris* by Schering-Plough), bepotastine besilate (*Bepreve* by ISTA Pharmaceuticals), besifloxacin hydrochloride (*Besivance* by Bausch & Lomb), canakinumab (*Ilaris* by Novartis), chenodiol (*Chenodal* by Manchester Pharmaceuticals), collagenase *Clostridium histolyticum* (*Xiaflex* by Auxilium), dalfampridine (*Ampyra* by Acorda), dronedarone (*Multaq* by Sanofi-Aventis), ferumoxytol (*Feraheme* by AMAG Pharmaceuticals), gadofosveset trisodium (*Ablavar* by DuPont Radiopharmaceuticals), golimumab (*Simponi* by Centocor Ortho Biotech), human papillomavirus (types 16, 18), bivalent vaccine (*Cervarix* by GlaxoSmithKline), iloperidone (*Fanapt* by Vanda Pharmaceuticals), influenza a (H1N1) vaccine injection and intranasal, ecallantide (*Kalbitor* by Dyax Corp.), liraglutide (*Victoza* by Novo Nordisk), ofatumumab (*Arzerra* by GlaxoSmithKline), pazopanib hydrochloride (*Votrient* by GlaxoSmithKline), pitavastatin (*Livalo* by Kowa Pharmaceuticals), pralatrexate (*Folotryn* by Allos Therapeutics), prasurgel hydrochloride (*Effient* by Eli Lilly and Company), romidepsin (*Istodax* by Gloucester Pharmaceuticals), saxagliptin hydrochloride (*Onglyza* by Bristol-Myers Squibb), tapentadol hydrochloride (*Nucynta* by PriCara), telavancin hydrochloride (*Vibativ* by Astellas), tocilizumab (*Acterma* by Genentech), tolvaptan (*Samsca* by Otsuka), ustekinumab (*Stelara* by Centocor Ortho Biotech), velaglucerase alfa (*VPRIV* by Shire Human Genetic Therapies), and vigabatrin (*Sabril* by Lundbeck).

As this edition goes to press, we continue to update our database daily for use in future editions and formats of *DFC*. We also continue to expand our extensive library of drug information resources to remain the full service drug information provider that our customers have come to expect. However, this can only be accomplished with feedback from the loyal health care professionals who use our information on a daily basis. Comments, criticisms, and suggestions are always welcome and encouraged. Please call or visit us at www.factsandcomparisons.com.

Renee M. Wickersham
Senior Managing Editor,
Content Development

Kirsten K. Novak
Managing Editor

Introduction

Drug Facts and Comparisons® is a comprehensive drug information compendium. Organized by therapeutic drug class, the format is designed to provide a wide scope of drug information in a manner that facilitates evaluations and comparisons. A comprehensive index, a detailed table of contents for each chapter, and numerous cross references within monographs enable the reader to quickly locate needed information.

Editorial Policy

The principal editorial policy remains unchanged from the inception of *Drug Facts and Comparisons*® in 1945: Accurate, unbiased information; concise, standardized presentation; comparative, objective format; timely delivery. Review of FDA-approved product labeling, thousands of biomedical journal articles and textbooks, and policies and recommendations from many authoritative and official groups (eg, Centers for Disease Control; National Academy of Sciences; Joint National Committee on Detection, Evaluation, and Treatment of High Blood Pressure; National Heart, Lung and Blood Institute; American Thoracic Society; National Cancer Institute; FDA Office of Orphan Products Development; Food and Drug Administration) form the base of evaluation of information for *Drug Facts and Comparisons*®. (See the end of the Introduction for a list of references.)

Editorial policy is guided by the distinguished Facts & Comparisons™ Editorial Advisory Panel. This is an authoritative group of nationally and internationally recognized clinicians, scholars, scientists, physicians, pharmacists, and pharmacologists. In addition, many other prominent health care professionals serve on various expert panels and provide review in their specific areas of expertise for *Drug Facts and Comparisons*®. Indications and dosage recommendations are FDA-approved unless otherwise specified. Legitimate "Off-label" uses and dosages are included when appropriate and given special emphasis. They are intended to aid the health care professional in quickly identifying information regarding a specific off-label use. Inclusion of off-label drug information is intended for research purposes and not to be interpreted as a recommendation. The reader should always refer to primary literature for more comprehensive information prior to patient care decisions. In some instances, where noted, there is poor documentation to support the use. (See How to Use Drug Facts and Comparisons.) Input from an expert panel on drug interactions is also a feature.

This collection of wisdom and the world drug information literature is then molded and refined into the *Drug Facts and Comparisons*® database, monographs, and product listings. Many sources of drug information are constantly monitored so that *Drug Facts and Comparisons*® contains the most comprehensive, current drug information database available. There is not a more complete drug information compendium available presenting such clinical prescribing and drug product information.

Most of the products listed in *Drug Facts and Comparisons*® 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. When more than one company distributes a generic product, the generic product name is listed, followed by "Various, eg," in parentheses with a selected list of distributors. Listing of specific products is an indication only of market availability and is not an endorsement or recommendation. Most products listed have national or significant regional distribution.

Products that contain the same active ingredients are listed together for comparison and as an aid in product selection. However, drug product interchange is regulated by state laws; listing of products together does not imply that products are therapeutically equivalent or legally interchangeable. Cau-

tion is particularly advised when attempting to compare extended-release or delayed-release dosage forms.

How To Use *Drug Facts And Comparisons®*

Efficient use of *Drug Facts and Comparisons® (DFC)* requires an understanding of its organization and format.

Organization:

Information in *DFC* is organized by therapeutic use. Each of the 14 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. Drugs with multiple uses may be listed in more than one section of the book.

Drug Monographs:

Prescribing information is presented in comprehensive drug monographs. General information on a group of closely related drugs (eg, ACE inhibitors) may be presented in a group monograph. Specific information for each drug follows the product listing; often there are separate monographs for each route of administration. All monographs are divided into sections identified with bold titles for ease in locating the desired information.

Indications: All indications or uses listed are FDA-approved unless specifically designated as "off-label uses." Inclusion of off-label drug information is intended for research purposes and not to be interpreted as a recommendation.

Off-label uses – Some off-label uses include numbered documentation ratings. Definitions associated with each rating appear below.

Documentation Levels Used for Off-label Uses

Number	Documentation	Definition
1	Good	Efficacy, safety risks, and optimal dosing are clearly identified in appropriate population as evidenced by consistent favorable data from at least one well-designed, controlled trial and/or dramatic results from uncontrolled experiments supported by guidelines published by expert panels.
2	Fair	Therapy represents rational use as evidenced by *consistent favorable* clinical reports/trials but further study is needed due to at least 1 of the following factors: • Appropriate candidates for therapy have not been clearly identified. • Optimal dosage and duration of therapy have not been consistently studied or determined. • Some safety issues require further investigation (eg, bacterial resistance).
3	Significant safety concerns exist	Efficacy is evidenced by some clinical reports, but significant safety concerns (eg, adverse events or drug interactions) must be considered prior to use. Significant safety data have been identified by controlled or noncontrolled reports and/or FDA or manufacturer safety notifications (eg, black box warnings).

Documentation Levels Used for Off-label Uses		
Number	Documentation	Definition
4	Insufficient	Rational use cannot be established as evidenced by data in limited patient population (fewer than 30 patients) or inconsistent results. Assessment of appropriate patient population, dose, or efficacy cannot be adequately determined. In addition, significant safety data have been identified by FDA or manufacturer safety notifications (eg, black box warnings).
5	Poor	Use is not recommended based on data that indicate use is considered unsafe or noneffective.

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

Off-label uses – When "off-label uses" with documentation ratings are listed in the Indications section, a summary of the corresponding dosing information will appear in the Administration and Dosage section. The documentation rating will be repeated (see Documentation Levels Used for Off-label Uses). Inclusion of dosing information for off-label uses is intended for research purposes and not to be interpreted as a recommendation.

Additional off-label information specific to dosing may also appear in the Administration and Dosage sections.

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

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-lab test and drug-food 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.

Index:

The alphabetical index includes page references for all drugs by their generic name, brand name, synonyms, common abbreviations and therapeutic group names. Generic names are listed in bold type face for easy identification.

Product Listings:

Individual products are listed at the beginning of each monograph. The format and components of the product listings are discussed below and illustrated on the opposite page.

NOTE: Products that contain the same active ingredients are listed together for comparison and as an aid in product selection. However, drug product interchange is regulated by state laws; listing of products together does not imply that products are therapeutically equivalent or legally interchangeable. Caution is particularly advised when attempting to compare extended-release or delayed-release dosage forms.

1. Products are grouped by dosage form and strength.
2. Brand name products with the same amount of active ingredient and in the same doseform are listed in alphabetical order.
3. The name of the distributor is given in parentheses next to the product name.
4. Products available by their generic name from multiple sources are indicated as available from (Various) distributors and in selected cases, examples of generic manufacturers are listed.
5. Package sizes are given for all dosage forms and strengths of each product.
6. Product identification imprint codes are listed in parentheses.
7. Cross references to the appropriate drug monograph(s) for complete prescribing information appear at the beginning of the monograph.
8. Controlled substances are designated by their schedule (*c-II, c-III, c-IV,* or *c-V*).
9. Distribution status of products is indicated as *Rx* or *otc* (products listed as *otc* may include nutritional or dietary supplements).
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 active ingredients are listed together.

Aminopenicillins

AMOXICILLIN

Rx	**Amoxil** (SK-Beecham)	**Tablets:** 500 mg (as trihydrate)	(Amoxil 500). Film-coated. Capsule shape. Pink. In 20s, 100s, 500s
		875 mg (as trihydrate)	(Amoxil 875). Film coated, scored. Capsule shape. Pink. In 20s, 100s, 500s.
Rx	**Amoxicillin** (Various, eg, Biocraft, Major, Rugby, Teva, URL)	**Capsules:** 250 mg (as trihydrate)	In 21s, 30s, 100s, 250s, 500s, 1000s and UD 45s and 100s.
Rx	**Amoxil** (SK-Beecham)		(Amoxil 250). Blue and pink. In 100s, 500s and UD 100s.
Rx	**Trimox** (Apothecon)		In 30s, 100s, 500s and UD 100s.
Rx	**Wymox** (Wyeth-Ayerst)		(Wyeth 559). Gray and green. In 100s and 500s.
Rx	**Amoxicillin** (Various, eg, Biocraft, Major, Rugby, Teva, URL)	**Capsules:** 500 mg (as trihydrate)	In 21s, 30s, 50s, 100s, 250s, 500s and UD 45s and 100s.
Rx	**Amoxil** (SK-Beecham)		(Amoxil 500). Blue and pink. In 100s, 500s and UD 100s.
Rx	**Trimox** (Apothecon)		In 30s, 100s, 500s and UD 100s.
Rx	**Wymox** (Wyeth-Ayerst)		(Wyeth 560). Gray and green. In 50s and 500s.
Rx	**Amoxil Pediatric Drops** (SK-Beecham)	**Powder for Oral Suspension:** 50 mg/ml (as trihydrate) when reconstituted	Sucrose. Bubble gum flavor. In 15 and 30 ml.
Rx	**Trimox Pediatric Drops** (Apothecon)		Sucrose. In 15 ml.
Rx	**Amoxicillin** (Various, eg, Biocraft, Major, Teva, URL)	**Powder for Oral Suspension:** 125 mg/5 ml (as trihydrate) when reconstituted	In 80, 100, 150 and 200 ml.
Rx	**Amoxil** (SK-Beecham)		Sucrose. Strawberry flavor. In 80, 100 and 150 ml and UD 5 ml.
Rx	**Trimox** (Apothecon)		Sucrose. In 80, 100 and 150 ml.
Rx	**Wymox** (Wyeth-Ayerst)		Sucrose. In 100 and 150 ml.
Rx	**Amoxicillin** (Various, eg, Biocraft, Major, Teva, URL)	**Powder for Oral Suspension:** 250 mg/5 ml (as trihydrate) when reconstituted	In 80, 100, 150 and 200 ml.
Rx	**Amoxil** (SK-Beecham)		Sucrose. Bubble gum flavor. In 80, 100 and 150 ml and UD 5 ml.
Rx	**Trimox** (Apothecon)		Sucrose. In 80, 100 and 150 ml.
Rx	**Wymox** (Wyeth-Ayerst)		Sucrose. In 100 and 150 ml.

For complete prescribing information, refer to the Penicillins group monograph.

the advantage of more complete absorption than ampicillin, a 3-times a day regimen for most infections and less diarrhea than ampicillin.

COUGH PREPARATIONS

ANTITUSSIVE AND EXPECTORANT COMBINATIONS

Content given per tablet, 5 mL, or packet.

	Product & Distributor	Antitussive	Expectorant	Decongestant
Rx	**Levall Liquid**[1] (Athlon Pharmaceuticals[2])	20 mg carbetapentane citrate	100 mg guaifenesin	15 mg phenylephrine HCl
c-v	**Dihistine Expectorant Liquid** (Alpharma)	10 mg codeine phosphate	100 mg guaifenesin	30 mg pseudoephedrine HCl
c-v	**Guiatuss DAC Liquid**[1] (Various, eg, Alpharma, Ivax)			
c-v sf	**Halotussin DAC Syrup**[1] (Watson Laboratories)			
c-v sf	**Mytussin DAC Liquid**[1] (Morton Grove Pharmaceuticals)			
c-v	**Novagest Expectorant with Codeine Liquid**[1] (Major)			
c-iii	**Nucofed Expectorant Syrup**[1] (Monarch)			
c-iii	**Nucotuss Expectorant Syrup**[1] (Alpharma)	12.5% alcohol. In 473 mL.		
c-v	**Tussirex Syrup** (Scot-Tussin)	10 mg codeine phosphate	83.3 mg sodium citrate	4.17 mg phenylephrine HCl
c-v sf	**Tussirex Sugar Free Liquid** (Scot-Tussin)			
Rx	**Donatussin Syrup**[1] (Laser)	7.5 mg dextromethorphan HBr	100 mg guaifenesin	10 mg phenylephrine HCl
otc sf	**Tussex Cough Syrup**[1] (Alpharma)	10 mg dextromethorphan HBr	100 mg guaifenesin	5 mg phenylephrine HCl
Rx	**Tussafed Ex Syrup**[1] (Everett Laboratories)	30 mg dextromethorphan HBr	200 mg guaifenesin	10 mg phenylephrine HCl
otc	**Guiatuss CF Syrup**[1] (Alpharma)	10 mg dextromethorphan HBr	100 mg guafenesin	30 mg pseudoephedrine HCl
otc	**Robafen CF Syrup**[1] (Major)			
otc	**Robitussin CF Syrup**[1] (Whitehall-Robins)			

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Product labeling; thousands of biomedical articles; policies, guidelines and recommendations from many authoritative groups; and textbooks are used to form the base of evaluation of information for *Drug Facts and Comparisons,* including the following:

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