DRUG FACTS AND COMPARISONS

2007

POCKET VERSION

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HOW TO USE

Drug monographs in *Drug Facts and Comparisons®, Pocket Version* are arranged by use. Drugs with similar therapeutic or pharmacologic characteristics have been grouped together to allow the health care provider to compare these drugs easily and determine the most appropriate drug therapy. Standard sections within the monographs occur in a consistent format. Once the user is familiar with the organization of the data, the desired information can be located quickly.

Monograph Organization

1. *Therapeutic class:* Drugs that share the same therapeutic class will share a common title that appears on the right-hand pages. The monograph title appears on the left-hand pages. If there is no shared class, the monograph title will repeat on the right-hand page.
2. *Drug name:* Generic names and any common synonyms appear in a horizontal bar that introduces a new monograph. Synonyms follow the generic name in parentheses and are separated by semicolons.
3. *Product table:* Doseforms and strengths of generic drugs are listed in the left column with their schedules (eg, *Rx, otc, c-ii*). If more than one generic entity is included in the monograph (eg, beta blockers), the drugs appear in all caps with specific information underneath it. The more common trade names, with their specific manufacturers/distributors, are listed in the right-hand column. If the drug is available generically, the word "Various" appears at the beginning of the trade name listing.
4. *Warning box:* Potentially life-threatening reactions specified in the product labeling will appear in a box. *Not included in sample.*
5. *Indications:* All FDA-approved indications are included. In addition, off-label uses with substantial documentation about dosing may appear under the term "Unlabeled uses."
6. *Administration and Dosage:* Appropriate dosage, dosage range, etc. is included. When available, specific information for administration in situations such as renal impairment, elderly patients, etc., is included.
7. *Actions:* This section includes a brief discussion of significant pharmacologic and pharmacokinetic information is included.
8. *Contraindications:* All known contraindications are included.
9. *Warnings:* This section includes a brief description of major warnings associated with the drug. Standard sections (eg, Pregnancy, Lactation, Children) appear at the end of this section. The Pregnancy section generally only lists the Standard Pregnancy Category (A, B, C, D, or X). A description of these categories can be found in the Appendix.
10. *Precautions:* Potential conditions for which the patient should be cautioned (eg, photosensitivity) are included, as well as other significant situations where caution is warranted.
11. *Drug Interactions:* Drugs that may interact (affect or be affected by the interacting agent) are listed. Lab test and drug/food interactions also are included.
12. *Adverse Reactions:* Where possible, reactions that occur in 3% or more of patients have been listed. When percentages are not available, significant reactions not discussed in Warnings or Precautions are included.

CYCLOBENZAPRINE HCl

Tablets: 10 mg (Rx) — Various, *Flexeril* (Merck)

Indications

Musculoskeletal conditions: Adjunct to rest and physical therapy for relief of muscle spasm associated with acute painful musculoskeletal conditions.

Unlabeled uses: Cyclobenzaprine (10 to 40 mg/day) appears to be a useful adjunct in the management of the fibrositis syndrome.

Administration and Dosage

Give 10 mg 3 times daily (range, 20 to 40 mg daily in divided doses). Do not exceed 60 mg/day. Do not use longer than 2 or 3 weeks.

Actions

Pharmacology: Cyclobenzaprine, structurally related to the tricyclic antidepressants (TCAs), relieves skeletal muscle spasm of local origin without interfering with muscle function. It is ineffective in muscle spasm due to CNS disease. The net effect is a reduction of tonic somatic motor activity, influencing both gamma and alpha motor systems.

Pharmacokinetics: Cyclobenzaprine is well absorbed after oral administration, but there is a large intersubject variation in plasma levels. Peak plasma levels are reached in 4 to 6 hours. The onset of action occurs in 1 hour with a duration of 12 to 24 hours. It is highly bound to plasma proteins, extensively metabolized primarily to glucuronide-like conjugates and excreted primarily via the kidneys. Elimination half-life is 1 to 3 days.

Contraindications

Hypersensitivity to cyclobenzaprine; concomitant use of monoamine oxidase (MAO) inhibitors or within 14 days after their discontinuation; acute recovery phase of MI and in patients with arrhythmias, heart block, or conduction disturbances or CHF; hyperthyroidism.

Warnings

Spasticity: Cyclobenzaprine is not effective in the treatment of spasticity associated with cerebral or spinal cord disease, or in children with cerebral palsy.

Duration: Use only for short periods (up to 2 or 3 weeks); effectiveness for more prolonged use is not proven.

Similarity to TCAs: Cyclobenzaprine is closely related to the TCAs. In short-term studies for indications other than muscle spasm associated with acute musculoskeletal conditions, and usually at doses greater than those recommended, some of the more serious CNS reactions noted with the TCAs have occurred.

Pregnancy: Category B.

Lactation: It is not known whether cyclobenzaprine is excreted in breast milk.

Children: Safety and efficacy in children < 15 years of age have not been established.

Precautions

Anticholinergic effects: Because of its anticholinergic action, use with caution in patients with a history of urinary retention, angle-closure glaucoma, and increased intraocular pressure.

Hazardous tasks: May impair mental or physical abilities required for performance of hazardous tasks; patients should observe caution while driving or performing other tasks requiring alertness, coordination, and physical dexterity.

Drug Interactions

Drugs that may interact with cyclobenzaprine HCl include MAO inhibitors and TCAs.

Adverse Reactions

Adverse reactions occurring in ≥ 3% of patients include drowsiness, dizziness, fatigue, tiredness, asthenia, blurred vision, headache, nervousness, confusion, dry mouth, nausea, constipation, dyspepsia, unpleasant taste, purpura, bone marrow depression, leukopenia, eosinophilia, thrombocytopenia, elevation and lowering of blood sugar levels, and weight gain or loss.

PREFACE

The Pocket Version of *Drug Facts and Comparisons® (DFC)* is an abridged version of the full *DFC* publication designed for quick reference by the health care professional. The purpose of the *DFC Pocket Version* is to provide an easy-to-use, concise, portable reference that can be utilized in daily practice. It is not intended to replace the complete information found in *DFC*; however, it provides the same reliable source of drug information.

In addition to the extensive review panel for *DFC*, a separate panel of drug information specialists and hospital pharmacists was established to determine which drug monographs would be most valuable to the health care professional along with the data for each drug needed most. The book is arranged therapeutically in 13 chapters in a consistent format. Single-agent monographs have been pared down to provide the essential information that a health care provider needs to aid in drug therapy decisions. Product tables that list trade names, doseforms, strengths, and manufacturers are included at the beginning of each monograph. Group monographs contain product information and dosing instructions for each of the drugs in a specific class (eg, beta blockers). Indications, administration and dosage, actions, contraindications, warnings, drug interactions, and significant adverse reactions (those occurring in at least 3% of patients) also are included for all monographs. The useful tables that are so common to *DFC* have, for the most part, been retained in the Pocket Version.

Appendix material (eg, Management of Overdosage, FDA Pregnancy Categories) also is available for reference. A comprehensive index helps the reader reach the desired information quickly and easily.

Wolters Kluwer Health hopes health care providers find *Drug Facts and Comparisons® Pocket Version* a valuable tool in daily practice. As always, comments and suggestions are appreciated.

Cathy H. Reilly
Vice President and Publisher

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