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- QUIZZES

home > drugs a-z list > flexeril (cyclobenzaprine hcl) side effects drug center



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Flexeril

Side Effects Center

Drug Description

Indications & Dosage

Side Effects & Drug Interactions

Warnings & Precautions

Overdosage & Contraindications

Clinical Pharmacology

Medication Guide

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Patient

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- Toradol
- Ultracet
- Ultram ER
- Vicoprofen
- Zanaflex

Health Resources

- « Previous
- 1
- 2
- 3
- 4
- 5
- 6
- 7
- 8
- 9
- 10
- 11
- 12
- 13
- Next »

[Flexeril User Reviews >>](#)

Flexeril



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Medical Editor: [John P. Cunha, DO, FACOEP](#)

Medical Editor: [John P. Cunha, DO, FACOEP](#)

Flexeril is available as tablets to be taken orally. Flexeril (cyclobenzaprine) is closely related to the tricyclic antidepressants and therefore should not be prescribed with or within two weeks of taking monoamine oxidase (MAO) inhibitor drugs. Flexeril may increase the effects of alcohol, barbiturates, and other central nervous system depressants. There are no adequate studies on the use of Flexeril in pregnant women. It is not known if Flexeril is secreted in milk. However, because Flexeril is related to tricyclic antidepressants and some of these are excreted in breast milk, caution is advised in nursing mothers.

Our Flexeril Side Effects Drug Center provides a comprehensive view of available drug information on the potential side effects when

Prescribing Information

- Drug Description
- Indications & Dosage
- Side Effects & Drug Interactions
- Warnings & Precautions
- Overdosage & Contraindications
- Clinical Pharmacology
- Medication Guide

For Patients

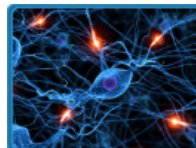
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- Flexeril in Detail with Side Effects

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Vaccine Safety

taking this medication.

This is not a complete list of side effects and others may occur. Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

Flexeril in Detail - Patient Information: Side Effects

Get emergency medical help if you have any of these **signs of an allergic reaction**: hives; difficulty breathing; swelling of your face, lips, tongue, or throat.

Stop using cyclobenzaprine and call your doctor at once if you have any of these serious side effects:

- o fast, pounding, or uneven heartbeats;
- o chest pain or heavy feeling, pain spreading to the arm or shoulder, nausea, sweating, general ill feeling;
- o sudden numbness or weakness, especially on one side of the body;
- o sudden headache, confusion, problems with vision, speech, or balance;
- o feeling light-headed, fainting;
- o confusion, weakness, lack of coordination;
- o nausea, stomach pain, low fever, loss of appetite, dark urine, clay-colored stools, jaundice (yellowing of the skin or eyes);
- o seizure (convulsions);
- o unusual thoughts or behavior, hallucinations (seeing things); or
- o easy bruising or bleeding, unusual weakness.

Less serious side effects may include:

- o dry mouth or throat;
- o blurred vision;
- o drowsiness, dizziness, tired feeling;
- o loss of appetite, stomach pain, nausea;
- o diarrhea, constipation, gas; or
- o muscle weakness.

This is not a complete list of side effects and others may occur. Tell your doctor about any unusual or bothersome side effect. You may report side effects to FDA at 1-800-FDA-1088.

[Read the entire detailed patient monograph for Flexeril \(Cyclobenzaprine Hcl\).](#)

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Flexeril Overview - Patient Information: Side Effects

SIDE EFFECTS: Drowsiness, dizziness, dry mouth, constipation, or tiredness may occur. If any of these effects persist or worsen, tell your doctor or pharmacist promptly. Remember that your doctor has prescribed this medication because he or she has judged that the benefit to you is greater than the risk of side effects. Many people using this medication do not have serious side effects.

Tell your doctor right away if you have any serious side effects, including: fast/irregular heartbeat, mental/mood changes (such as confusion, hallucinations), trouble urinating.

A very serious allergic reaction to this drug is rare. However, get medical help right away if you notice any symptoms of a serious allergic reaction, including: rash, itching/swelling (especially of the face/tongue/throat), severe dizziness, trouble breathing.

This is not a complete list of possible side effects. If you notice other effects not listed above, contact your doctor or pharmacist.

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Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

In Canada - Call your doctor for medical advice about side effects. You may report side effects to Health Canada at 1-866-234-2345.

[Read the entire patient information overview for Flexeril \(Cyclobenzaprine Hcl\)](#)

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Flexeril FDA Prescribing Information: Side Effects (Adverse Reactions)

SIDE EFFECTS

Incidence of most common adverse reactions in the 2 double-blind, placebo-controlled 5 mg studies (incidence of > 3% on FLEXERIL 5 mg):

	FLEXERIL 5 MG N=464	FLEXERIL 10 MG N=249	PLACEBO N=469
Drowsiness	29%	38%	10%
Dry Mouth	21%	32%	7%
Fatigue	6%	6%	3%
Headache	5%	5%	8%

Adverse reactions which were reported in 1% to 3% of the patients were: abdominal pain, acid [regurgitation](#), constipation, diarrhea, dizziness, nausea, irritability, mental acuity decreased, nervousness, [upper respiratory infection](#), and [pharyngitis](#).

The following list of adverse reactions is based on the experience in 473 patients treated with FLEXERIL 10 mg in additional controlled clinical studies, 7607 patients in the postmarketing surveillance program, and reports received since the drug was marketed. The overall incidence of adverse reactions among patients in the surveillance program was less than the incidence in the controlled clinical studies.

The adverse reactions reported most frequently with FLEXERIL were drowsiness, dry mouth and dizziness. The incidence of these common adverse reactions was lower in the surveillance program than in the controlled clinical studies:

	CLINICAL STUDIES WITH FLEXERIL 10 MG	SURVEILLANCE PROGRAM WITH FLEXERIL 10 MG
Drowsiness	39%	16%
Dry Mouth	27%	7%
Dizziness	11%	3%

Among the less frequent adverse reactions, there was no appreciable difference in incidence in controlled clinical studies or in the surveillance program. Adverse reactions which were reported in 1% to 3% of the patients were: fatigue/tiredness, [asthenia](#), nausea, constipation, [dyspepsia](#), unpleasant taste, blurred vision, headache, nervousness, and confusion. The following adverse reactions have been reported in post-marketing experience or with an incidence of less than 1% of patients in clinical trials with the 10 mg tablet:

Body as a Whole: [Syncope](#); [malaise](#).

Cardiovascular: [Tachycardia](#); [arrhythmia](#); vasodilatation; palpitation; [hypotension](#).

Digestive: Vomiting; [anorexia](#); diarrhea; [gastrointestinal](#) pain; [gastritis](#); thirst; [flatulence](#); [edema](#) of the tongue; abnormal liver function and rare reports of [hepatitis](#), [jaundice](#) and cholestasis.

Hypersensitivity: [Anaphylaxis](#); [angioedema](#); [pruritus](#); facial edema; [urticaria](#); rash.

Musculoskeletal: Local weakness.

Nervous System and Psychiatric: Seizures, [ataxia](#); [vertigo](#); [dysarthria](#); tremors; [hypertonia](#); convulsions; muscle [twitching](#); disorientation; insomnia; depressed mood; abnormal sensations; anxiety; agitation; [psychosis](#), abnormal thinking and dreaming; hallucinations; excitement; [paresthesia](#); [diplopia](#), serotonin syndrome.

Skin: Sweating.

Special Senses: [Ageusia](#); [tinnitus](#).

Urogenital: Urinary frequency and/or retention.

Causal Relationship Unknown

Other reactions, reported rarely for FLEXERIL under circumstances where a causal relationship could not be established or reported for other tricyclic drugs, are listed to serve as alerting information to physicians:

Body as a whole: Chest pain; edema.

Cardiovascular: [Hypertension](#); myocardial [infarction](#); [heart block](#); [stroke](#).

Digestive: [Paralytic ileus](#), tongue discoloration; stomatitis; parotid swelling.

Endocrine: Inappropriate [ADH](#) syndrome.

Hematic and Lymphatic: [Purpura](#); bone marrow depression; [leukopenia](#); [eosinophilia](#); [thrombocytopenia](#).

Metabolic, Nutritional and Immune: Elevation and lowering of blood sugar levels; weight gain or loss.

Musculoskeletal: [Myalgia](#).

Nervous System and Psychiatric: Decreased or increased [libido](#); abnormal [gait](#); delusions; aggressive behavior; paranoia; [peripheral neuropathy](#); [Bell's palsy](#); alteration in [EEG](#) patterns; extrapyramidal symptoms.

Respiratory: [Dyspnea](#).

Skin: Photosensitization; [alopecia](#).

Urogenital: Impaired urination; [dilatation](#) of [urinary tract](#); [impotence](#); testicular swelling; [gynecomastia](#); breast enlargement; [galactorrhea](#).

Drug Abuse And Dependence

Pharmacologic similarities among the tricyclic drugs require that certain [withdrawal symptoms](#) be considered when FLEXERIL is administered, even though they have not been reported to occur with this drug. Abrupt cessation of treatment after prolonged administration rarely may produce nausea, headache, and malaise. These are not indicative of addiction.

[Read the entire FDA prescribing information for Flexeril \(Cyclobenzaprine Hcl\)](#)

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« Previous 1 2 3 4 5 6 7 8 9 10 11 12 13 Next »

Next: Drug Description

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- [Drug Description](#)
- [Indications & Dosage](#)
- [Side Effects & Drug Interactions](#)
- [Warnings & Precautions](#)
- [Overdosage & Contraindications](#)
- [Clinical Pharmacology](#)
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- [Flexeril Side Effects Center](#)
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- [Flexeril Overview including Precautions](#)
- [Flexeril FDA Approved Prescribing Information including Dosage](#)

Flexeril - User Reviews**Flexeril User Reviews**

Now you can gain knowledge and insight about a drug treatment with Patient Discussions.

Here is a collection of user reviews for the medication Flexeril sorted by most helpful. ?

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Report Problems to the Food and Drug Administration

You are encouraged to report negative side effects of prescription drugs to the FDA. Visit the [FDA MedWatch](#) website or call 1-800-FDA-1088.

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