DISCLAIMER

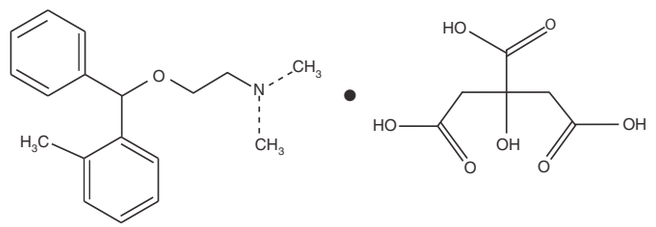
All labeling reflected on this website is for informational and promotional purposes only. It is not intended to be used by healthcare professionals or patients for the purpose of prescribing or administering these products. Questions regarding the current content of product labeling should be directed to Akorn's Customer Service department at 800.932.5676.

ORPHENADRINE CITRATE INJECTION, USP

℞ only

DESCRIPTION:

Orphenadrine citrate is the citrate salt of orphenadrine ((±)-N, N-Dimethyl-2-[(o-methyl-α-phenylbenzyl)oxy]ethylamine citrate (1:1)) with a molecular weight of 461.50; empirical formula $C_{18}H_{23}NO \cdot C_6H_8O_7$. The structural formula of orphenadrine citrate is:



It occurs as a white, crystalline powder having a bitter taste. It is practically odorless; sparingly soluble in water, slightly soluble in alcohol.

Orphenadrine citrate injection contains 60 mg of orphenadrine citrate in aqueous solution in each vial. Orphenadrine citrate injection also contains: sodium chloride USP, 5.8 mg; sodium metabisulfite NF, 2.0 mg; sodium hydroxide NF, to adjust pH (5.0 to 6.0); and water for injection USP, q.s. to 2 mL.

CLINICAL PHARMACOLOGY:

The mode of therapeutic action has not been clearly identified, but may be related to its analgesic properties. Orphenadrine citrate does not directly relax tense muscles in man. Orphenadrine citrate also possesses anti-cholinergic actions.

INDICATIONS AND USAGE:

Orphenadrine citrate injection is indicated as an adjunct to rest, physical therapy, and other measures for the relief of discomfort associated with acute painful musculoskeletal conditions. The mode of action of the drug has not been clearly identified, but may be related to its analgesic properties. Orphenadrine citrate does not directly relax tense skeletal muscles in man.

CONTRAINDICATIONS:

Contraindicated in patients with glaucoma, pyloric or duodenal obstruction, stenosing peptic ulcers, prostatic hypertrophy or obstruction of the bladder neck, cardio-spasm (megaesophagus) and myasthenia gravis.

Contraindicated in patients who have demonstrated a previous hypersensitivity to the drug.

WARNINGS:

Some patients may experience transient episodes of light-headedness, dizziness or syncope. Orphenadrine citrate may impair the ability of the patient to engage in potentially hazardous activities such as operating machinery or driving a motor vehicle; ambulatory patients should therefore be cautioned accordingly.

Orphenadrine citrate injection contains sodium metabisulfite, a sulfite that may cause allergic-type reactions including anaphylactic symptoms and life-threatening or less severe asthmatic episodes in certain susceptible people. The overall prevalence of sulfite sensitivity in the general population is unknown and probably low. Sulfite sensitivity is seen more frequently in asthmatic than nonasthmatic people.

PRECAUTIONS:

Confusion, anxiety and tremors have been reported in few patients receiving propoxyphene and orphenadrine concomitantly. As these symptoms may be simply due to an additive effect, reduction of dosage and/or discontinuation of one or both agents is recommended in such cases.

Orphenadrine citrate should be used with caution in patients with tachycardia, cardiac decompensation, coronary insufficiency, cardiac arrhythmias.

Safety of continuous long-term therapy with orphenadrine has not been established. Therefore, if orphenadrine is prescribed for prolonged use, periodic monitoring of blood, urine and liver function values is recommended.

Pregnancy: Teratogenic Effects: Pregnancy Category C.

Safe use of orphenadrine has not been established with respect to adverse effects upon fetal development. Therefore, orphenadrine should be used in women of childbearing potential and particularly during early pregnancy only when in the judgment of the physician the potential benefits outweigh the possible hazards.

Pediatric Use:

Safety and effectiveness in children have not been established; therefore, this drug is not recommended for use in the pediatric age group.

ADVERSE REACTIONS:

Adverse reactions of orphenadrine are mainly due to the mild anti-cholinergic action of orphenadrine, and are usually associated with higher dosage. Dryness of the mouth is usually the first adverse effect to appear. When the daily dose is increased, possible adverse effects include: tachycardia, palpitation, urinary hesitancy or retention, blurred vision, dilatation of pupils, increased ocular tension, weakness, nausea, vomiting, headache, dizziness, constipation, drowsiness, hypersensitivity reactions, pruritus, hallucinations, agitation, tremor, gastric irritation, and rarely urticaria and other dermatoses. Infrequently, an elderly patient may experience some degree of mental confusion. These adverse reactions can usually be eliminated by reduction in dosage. Very rare cases of aplastic anemia associated with the use of orphenadrine tablets have been reported. No causal relationship has been established.

Rare instances of anaphylactic reaction have been reported associated with the intramuscular injection of orphenadrine citrate injection.

DRUG ABUSE AND DEPENDENCE:

Orphenadrine has been chronically abused for its euphoric effects. The mood elevating effects may occur at therapeutic doses of orphenadrine.

OVERDOSAGE:

Orphenadrine is toxic when overdosed and typically induces anticholinergic effects. In a review of orphenadrine toxicity, the minimum lethal dose was found to be 2-3 grams for adults; however, the range of toxicity is variable and unpredictable. Treatment for orphenadrine overdose is evacuation of stomach contents (when necessary), charcoal at repeated doses, intensive monitoring, and appropriate supportive treatment of any emergent anticholinergic effects.

DOSAGE AND ADMINISTRATION:

INJECTION: Adults - One 2 mL vial (60 mg) intravenously or intramuscularly; may be repeated every 12 hours.

HOW SUPPLIED:

INJECTION: Boxes of 10 (NDC 17478-538-02) 2 mL vials, each vial containing 60 mg of orphenadrine citrate in aqueous solution.

Storage: Store at 20° to 25°C (68° to 77°F) [see USP Controlled Room Temperature]. Protect from light.

Single-dose vial. Discard unused portion.

AKORN

Manufactured by: **Akorn, Inc.**
Lake Forest, IL 60045

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