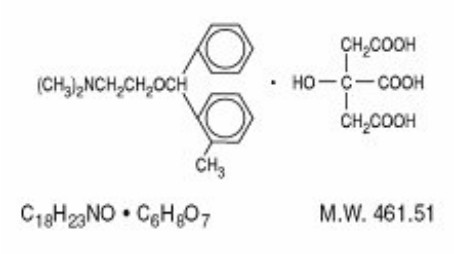
ORPHENADRINE CITRATE- orphenadrine citrate tablet
Medsource Pharmaceuticals

Orphenadrine Citrate Extended-Release Tablets

Rx only

DESCRIPTION

Orphenadrine citrate is the citrate salt of orphenadrine: (2-dimethyl-aminoethyl 2-methylbenzhydryl ether citrate). It occurs as a white, crystalline powder having a bitter taste. It is practically odorless; sparingly soluble in water, slightly soluble in alcohol and has a molecular weight of 461.51. The molecular formula $C_{18}H_{23}NO \cdot C_6H_8O_7$ is represented by the following structural formula:



Each orphenadrine citrate extended-release tablet contains 100 mg orphenadrine citrate. Orphenadrine citrate extended-release tablets also contain: calcium stearate, ethylcellulose and lactose monohydrate.

CLINICAL PHARMACOLOGY

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

INDICATIONS

Orphenadrine citrate is indicated as an adjunct to rest, physical therapy, and other measures for the relief of discomfort associated with acute painful musculo skeletal 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 extended-release tablets 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.

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 extended-release tablets should be used with caution in patients with tachycardia, cardiac decompensation, coronary insufficiency, cardiac arrhythmias.

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

PREGNANCY

Pregnancy Category C

Animal reproduction studies have not been conducted with orphenadrine citrate extended-release tablets. It is also not known whether orphenadrine citrate extended-release tablets can cause fetal harm when administered to a pregnant woman or can affect reproduction capacity. Orphenadrine citrate extended-release tablets should be given to a pregnant woman only if clearly needed.

PEDIATRIC USE

Safety and effectiveness in pediatric patients have not been established.

ADVERSE REACTIONS

Adverse reactions of orphenadrine citrate extended-release tablets are mainly due to the mild anti-cholinergic action of orphenadrine citrate extended-release tablets 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.

DRUG ABUSE AND DEPENDENCE

Orphenadrine citrate extended-release tablets have been chronically abused for their euphoric effects.[1] The mood elevating effects may occur at therapeutic doses of orphenadrine.[2]

OVERDOSAGE

Orphenadrine citrate extended-release tablets are toxic when overdosed and typically induces anti-cholinergic effects.[3] In a review of orphenadrine toxicity, the minimum lethal dose was found to be 2 to 3 grams for adults; however, the range of toxicity is variable and unpredictable.[4] Treatment for orphenadrine citrate extended-release tablets overdose is evacuation of stomach contents (when necessary), charcoal at repeated doses, intensive monitoring and appropriate supportive treatment of any emergent anti-cholinergic effects.[5]

DOSAGE AND ADMINISTRATION

Adults-Two tablets per day; one in the morning and one in the evening.

HOW SUPPLIED

Orphenadrine Citrate Extended-Release Tablets, 100 mg, white, round-shaped tablets debossed “E” over “22” on one side and plain on the other side

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

Dispense in tight, light-resistant containers as defined in the USP, with a child-resistant closure as required.

KEEP TIGHTLY CLOSED.

KEEP THIS AND ALL MEDICATION OUT OF THE REACH OF CHILDREN.

To report SUSPECTED ADVERSE REACTIONS, contact Sandoz Inc. at 1-800-525-8747 or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

Sandoz Inc.

Princeton, NJ 08540

OS8870

Rev. 09/09

MF0022REV09/09

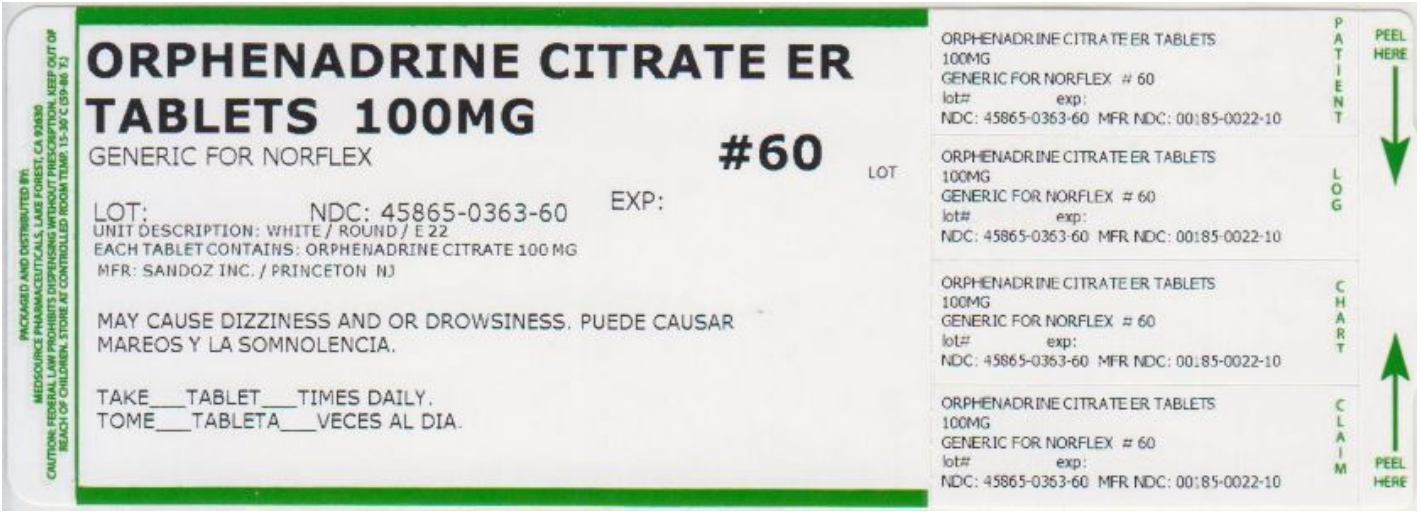
MG #14534

Orphenadrine Citrate Extended-Release Tablets, 100 mg x 60 Tablets - Label

ORPHENADRINE CITRATE ER TABLETS #60

GENERIC FOR NORFLEX

NDC: 45865-0363-60



ORPHENADRINE CITRATE
orphenadrine citrate tablet

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:45865-363(NDC:0185-0022)
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ORPHENADRINE CITRATE (UNII: X0A40N8I4S) (ORPHENADRINE - UNII:AL805O9OG9)	ORPHENADRINE CITRATE	100 mg

Inactive Ingredients

Ingredient Name	Strength
CALCIUM STEARATE (UNII: 776XM7047L)	
ETHYLCELLULOSES (UNII: 7Z8S9VYZ4B)	
LACTOSE MONOHYDRATE (UNII: EWQ57Q8I5X)	

Product Characteristics

Color	white (WHITE)	**Score**	no score
Shape	ROUND (ROUND)	**Size**	9mm
Flavor		**Imprint Code**	E;22
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:45865-363-49	100 in 1 BOTTLE; Type 0: Not a Combination Product		
2	NDC:45865-363-90	90 in 1 BOTTLE; Type 0: Not a Combination Product		
3	NDC:45865-363-60	60 in 1 BOTTLE; Type 0: Not a Combination Product		
4	NDC:45865-363-30	30 in 1 BOTTLE; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA040327	02/15/2000	

Labeler - Medsource Pharmaceuticals (833685915)

Registrant - Medsource Pharmaceuticals (833685915)

Establishment

Name	Address	ID/FEI	Business Operations
Medsource Pharmaceuticals		833685915	repack(45865-363)