

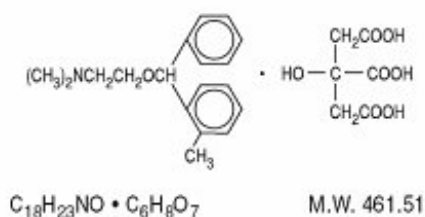
ORPHENADRINE CITRATE- orphenadrine citrate tablet, extended release Eon Labs, Inc.

Orphenadrine Citrate Extended-Release Tablets, USP

Rx Only

DESCRIPTION

Orphenadrine citrate, USP 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, USP contains 100 mg orphenadrine citrate, USP. Orphenadrine citrate extended-release tablets, USP 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 does not directly relax tense skeletal muscles in man. Orphenadrine citrate also possesses anti-cholinergic actions.

INDICATIONS AND USAGE

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

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.

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 citrate has not been established. Therefore, if orphenadrine citrate is 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. It is also not known whether orphenadrine citrate can cause fetal harm when administered to a pregnant woman or can affect reproduction capacity. Orphenadrine citrate 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 are mainly due to the mild anti-cholinergic action of orphenadrine citrate 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 has been chronically abused for its euphoric effects.[1] The mood elevating effects may occur at therapeutic doses of orphenadrine.[2]

OVERDOSAGE

Orphenadrine citrate is 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 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, USP, for oral administration, are available as

100 mg

White, round-shaped tablets debossed "E" over "22" on one side and plain on the other side and supplied as:

NDC 0185-0022-01 bottles of 100

NDC 0185-0022-10 bottles of 1000

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

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

KEEP TIGHTLY CLOSED.

KEEP 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.

Manufactured by

Sandoz Inc.

Princeton, NJ 08540

Rev. July 2017

MF0022REV07/2017

46193074

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

NDC 0185-0022-01

Orphenadrine Citrate Extended-Release Tablets, USP

100 mg

Rx only

100 Tablets

Sandoz

NDC 0185-0022-01

Orphenadrine Citrate Extended-Release Tablets, USP

100 mg

Rx Only
100 Tablets

SANDOZ

Each extended-release tablet contains:
Orphenadrine citrate, USP 100 mg.
USUAL DOSAGE: See accompanying literature for complete prescribing information.
Store at 20° to 25°C (68° to 77°F) [see USP Controlled Room Temperature].
Dispense contents in a tight, light-resistant container as defined in the USP with a child-resistant closure, as required.
KEEP TIGHTLY CLOSED.
KEEP OUT OF THE REACH OF CHILDREN. 46193072

Rev. 07/2017

Manufactured by
Sandoz Inc.
Princeton, NJ 08540

0185-0022-01

ORPHENADRINE CITRATE

orphenadrine citrate tablet, extended release

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	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)	
ETHYLCELLULOSE, UNSPECIFIED (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:0185-0022-10	1000 in 1 BOTTLE; Type 0: Not a Combination Product	02/15/2000	03/31/2024
2	NDC:0185-0022-01	100 in 1 BOTTLE; Type 0: Not a Combination Product	02/15/2000	

Marketing Information

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

Labeler - Eon Labs, Inc. (012656273)

Revised: 4/2018

Eon Labs, Inc.