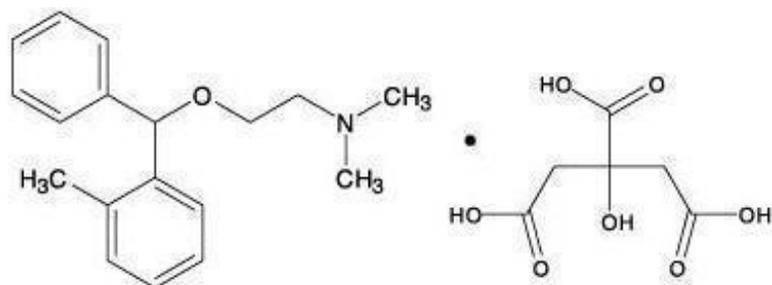


ORPHENADRINE CITRATE- orphenadrine citrate tablet, extended release
RxChange Co.

Orphenadrine Citrate Extended-Release Tablets
Gavis Pharmaceuticals, LLC.

DESCRIPTION

Orphenadrine citrate is the citrate salt of orphenadrine. It occurs as a white, crystalline powder having a bitter taste. It is practically odorless; sparingly soluble in water, slightly soluble in alcohol. The chemical name of orphenadrine citrate is (±)-N,N-Dimethyl-2-[(o-methyl- α -phenylbenzyl)oxy]ethylamine citrate (1:1) having molecular formula $C_{18}H_{23}NO \cdot C_6H_8O_7$ and molecular weight of 461.51. It has the following structural formula:



Each tablet for oral administration contains 100 mg orphenadrine citrate. Each Orphenadrine citrate extended release tablet contains the following inactive ingredients: hydroxypropyl methylcellulose, lactose monohydrate and magnesium stearate.

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

CONTRAINDICATIONS

Orphenadrine citrate extended-release tablets are contraindicated in patients with glaucoma, pyloric or duodenal obstruction, stenosing peptic ulcers, prostatic hypertrophy or obstruction of the bladder neck, cardio-spasm (mega-esophagus) and myasthenia gravis.

Orphenadrine citrate tablets are 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 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 has not been established. Therefore, if orphenadrine 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. It is also not known whether orphenadrine can cause fetal harm when administered to a pregnant woman or can affect reproduction capacity. Orphenadrine 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 are mainly due to the mild anticholinergic 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.

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 to 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

Adults

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

HOW SUPPLIED

Orphenadrine citrate extended-release tablets 100 mg are round, white to off-white tablets, debossed NL4 on one side and plain on the other side and are supplied as:

NDC 43386-480-24 in bottles of 100 tablets

NDC 43386-480-26 in bottles of 500 tablets

NDC 43386-480-28 in bottles of 1000 tablets

Storage and Handling

Store at 20°-25°C (68°-77°F) [see USP Controlled Room Temperature]. Dispense in a tight, light-resistant container.

Manufactured by

Novel Laboratories, Inc.

Somerset, NJ 08873

for GAVIS Pharmaceuticals, LLC

400 Campus Drive

Somerset, NJ 08873

GIN-480-01

Rev: 02/2011

PACKAGE LABEL.PRINCIPAL DISPLAY PANEL

RX CHANGE CO.

Item # 0274-60 NDC 33358-274-60
Lot #: 0000 Exp. Date: 0000
**Orphenadrine ER 100mg
#60, ER Tablets**

Each tablet contains: Orphenadrine ER 100mg
Identity: Round, white to off-white tablets, debossed "NL 4"
on one side and plain on the other side.

Dispense in this Tight/Light Resistant Container.
Store at Controlled Room Temperature (68-77F) **RX ONLY**

MFR: Novel Laboratories, Inc., Somerset, NJ 08873
WARNING: Keep out of reach of children.

Rx:221001

PEEL PEEL PEEL PEEL

ORPHENADRINE CITRATE

orphenadrine citrate tablet, extended release

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:33358-274(NDC:43386-480)
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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
HYPROMELLOSES (UNII: 3NXW29V3WO)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
LACTOSE MONOHYDRATE (UNII: EWQ57Q8I5X)	

Product Characteristics

Color	WHITE	Score	no score
Shape	ROUND	Size	10 mm
Flavor		Imprint Code	NL4
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:33358-274-60	60 in 1 BOTTLE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA040284	11/15/2014	

Labeler - RxChange Co. (781126805)

Establishment

Name	Address	ID/FEI	Business Operations
RxChange Co.		781126805	manufacture(33358-274)

Revised: 12/2014

RxChange Co.