ORPHENADRINE CITRATE- orphenadrine citrate tablet, extended release
Amneal Pharmaceuticals of New York LLC

Orphenadrine Citrate Extended-Release Tablets
(100 mg)

Rx only

DESCRIPTION

Orphenadrine citrate is the citrate salt of orphenadrine (2-dimethylaminoethyl-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.

Each orphenadrine citrate extended-release tablet contains 100 mg orphenadrine citrate, USP. Orphenadrine citrate extended-release tablets also contain ethylcellulose NF, povidone USP, lactose monohydrate NF, and magnesium stearate NF.

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 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 citrate. It is also not know 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 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, dilation 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.

To report SUSPECTED ADVERSE REACTIONS, contact Amneal Pharmaceuticals at 1-877-835-5472 or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

DRUG ABUSE AND DEPENDENCE

Orphenadrine has been chronically abused for its euphoric effects.[1] The mood elevating effects may occur at therapeutic doses of orphenadrine.[2]

OVERDOSAGE

Orphenadrine is toxic when overdosed and typically induces anticholinergic effects.[3] In a review of orphenadrine toxicity, the minimum lethal dose was found to be 2 grams to 3 grams for adults; however, the range of toxicity is variable and unpredictable.[4] 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.[5]

DOSAGE AND ADMINISTRATION

Orphenadrine citrate extended-release tablets: Adults - Two tablets per day; one in the morning and one in the evening.

HOW SUPPLIED

Orphenadrine Citrate Extended-release Tablets, **100 mg** - Each round, white, convex tablet imprinted with “G” on one side and “2011” on the other side.

They are available as follows:

Bottles of 100: NDC 0115-2011-01

Bottles of 500: NDC 0115-2011-02

Store at controlled room temperature 15° to 30°C (59° to 86°F).

Dispense in tightly-closed, light-resistant container (USP).

Distributed by:
Amneal Pharmaceuticals LLC
Bridgewater, NJ 08807

124-05

Rev. 01-2019-00

PRINCIPAL DISPLAY PANEL - 100 mg Tablet Bottle Label

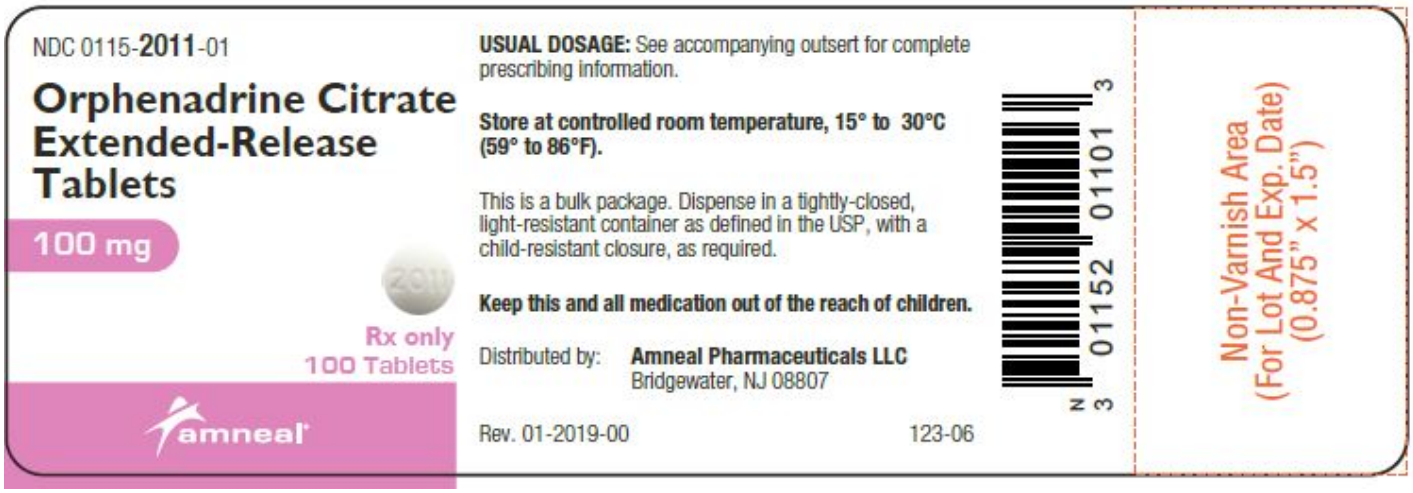
NDC 0115-2011-01

Orphenadrine Citrate Extended-Release Tablets

100 mg

Rx only

100 TABLETS



PRINCIPAL DISPLAY PANEL - 100 mg Tablet Bottle Label

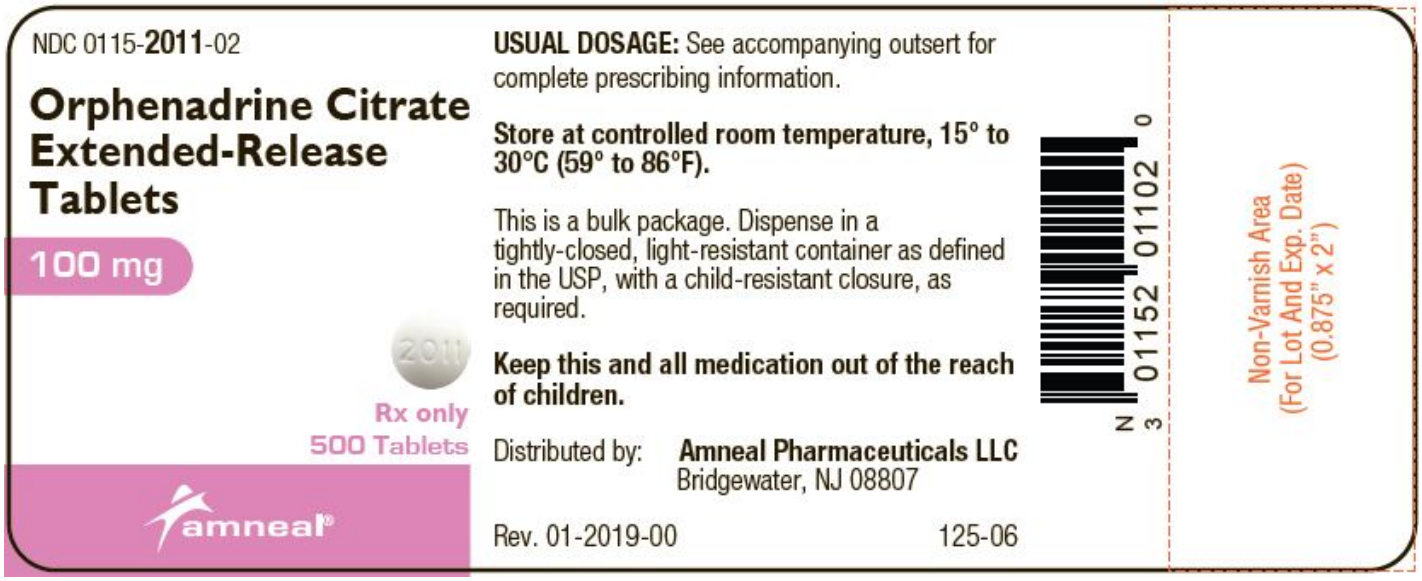
NDC 0115-2011-02

Orphenadrine Citrate Extended-Release Tablets

100 mg

Rx only

500 TABLETS



ORPHENADRINE CITRATE

orphenadrine citrate tablet, extended release

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:0115-2011
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**
ETHYLCELLULOSES (UNII: 7Z8S9VYZ4B)	
POVIDONE (UNII: FZ989GH94E)	
LACTOSE MONOHYDRATE (UNII: EWQ57Q8I5X)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	

Product Characteristics			
Color	WHITE	**Score**	no score
Shape	ROUND (convex)	**Size**	9mm
Flavor		**Imprint Code**	G;2011
Contains			

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:0115-2011-01	100 in 1 BOTTLE; Type 0: Not a Combination Product	06/23/2000	

2	NDC:0115-2011-02	500 in 1 BOTTLE; Type 0: Not a Combination Product	06/23/2000	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA040368	06/23/2000	

Labeler - Amneal Pharmaceuticals of New York LLC (123797875)

Establishment

Name	Address	ID/FEI	Business Operations
Amneal Pharmaceuticals of New York, LLC		123797875	ANALYSIS(0115-2011) , MANUFACTURE(0115-2011)

Establishment

Name	Address	ID/FEI	Business Operations
Reed-Lane		001819879	PACK(0115-2011)

Revised: 12/2019 Amneal Pharmaceuticals of New York LLC