ORPHENADRINE CITRATE - orphenadrine citrate tablet, extended release
STAT RX USA LLC

Rx only

DESCRIPTION

Orphenadrine citrate is the citrate salt of orphenadrine (2-dimethylaminoethyl 2-methyl-benzhydryl 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 tablet contains 100 mg orphenadrine citrate, USP. Orphenadrine citrate tablets also contain ethylcellulose NF, povidone USP, lactose monohydrate NF, and magnesium stearate NF.

ACTIONS

The mode of therapeutic action has not been clearly identified, but may be related to its analgesic properties. Orphenadrine citrate also possesses anticholinergic 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, cardiospasm (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.

PREGNANCY

Pregnancy category C

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

USAGE IN CHILDREN

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

PRECAUTIONS

Confusion, anxiety and tremors have been reported in a 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, or 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.

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, 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.

DOSAGE AND ADMINISTRATION

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

HOW SUPPLIED

Tablets 100 mg-Each round, white, convex tablet imprinted with "G" on one side and "2011" on the other side.

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).

Manufactured by: Impax Laboratories, Inc.
Hayward, California 94544

Dist. by: Global Pharmaceuticals
Division of IMPAX Laboratories, Inc.
Philadelphia, PA 19124

Rev. 01/00
124-02

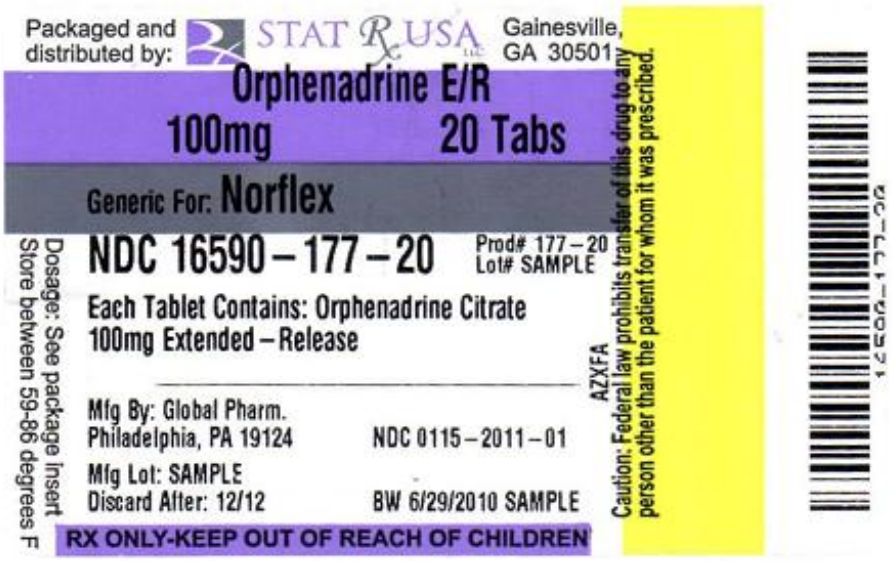
PACKAGE LABEL - ORPHENADRINE E/R - 100 MG - TABS

Orphenadrine
Citrate

Extended-Release Tablets

100 mg

Rx only



ORPHENADRINE CITRATE

orphenadrine citrate tablet, extended release

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:16590-177(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:16590-177-06	06 in 1 BOTTLE		
2	NDC:16590-177-10	10 in 1 BOTTLE		
3	NDC:16590-177-14	14 in 1 BOTTLE		
4	NDC:16590-177-15	15 in 1 BOTTLE		
5	NDC:16590-177-20	20 in 1 BOTTLE		
6	NDC:16590-177-30	30 in 1 BOTTLE		
7	NDC:16590-177-60	60 in 1 BOTTLE		
8	NDC:16590-177-62	84 in 1 BOTTLE		
9	NDC:16590-177-90	90 in 1 BOTTLE		
10	NDC:16590-177-71	100 in 1 BOTTLE		
11	NDC:16590-177-72	120 in 1 BOTTLE		

Marketing Information

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

Labeler - STAT RX USA LLC (786036330)

Establishment

Name	Address	ID/FEI	Business Operations
STAT RX USA LLC		786036330	relabel, repack

Revised: 4/2011 STAT RX USA LLC