

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

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**Orphenadrine Citrate Extended-release Tablets, 100 mg**

**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 30 NDC 42549-559-30

Bottles of 56 NDC 42549-559-56

Bottles of 60 NDC 42549-559-60

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

**GLOBAL®**

Rev. 01/00  
124-02

**Relabeling and Repackaging by:**

STAT Rx USA LLC  
Gainesville, GA 30501

Orphenadrine Citrate Extended-Release Tablets 100 mg

**Rx only**

Packaged and Distributed By: **STAT Rx USA** Gainesville, GA 30501  
**Orphenadrine E/R**  
**100mg 60 Tabs**  
 Generic For:  
**NDC 42549-559-60** Prod# 559-60 Lot# SAMPLE  
 Each Tablet Contains: Orphenadrine Citrate 100mg (Extended-Release)  
 Dist By: Global Pharm. Philadelphia, PA 19124 NDC 0115-2011-01  
 Mfg Lot: 27384 BW 12/1/2011 SAMPLE  
**RX ONLY-KEEP OUT OF REACH OF CHILDREN**

ORPHENADRINE CITRATE			
orphenadrine citrate tablet, extended release			
Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:42549-559(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

<b>Shape</b>	ROUND (CONVEX)	<b>Size</b>	9 mm
<b>Flavor</b>		<b>Imprint Code</b>	G;2011
<b>Contains</b>			

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:42549-559-30	30 in 1 BOTTLE		
2	NDC:42549-559-56	56 in 1 BOTTLE		
3	NDC:42549-559-60	60 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)

**Registrant** - PSS World Medical Inc. (101822682)

### Establishment

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