

## **ORPHENADRINE CITRATE- orphenadrine citrate injection, solution** **Sagent Pharmaceuticals**

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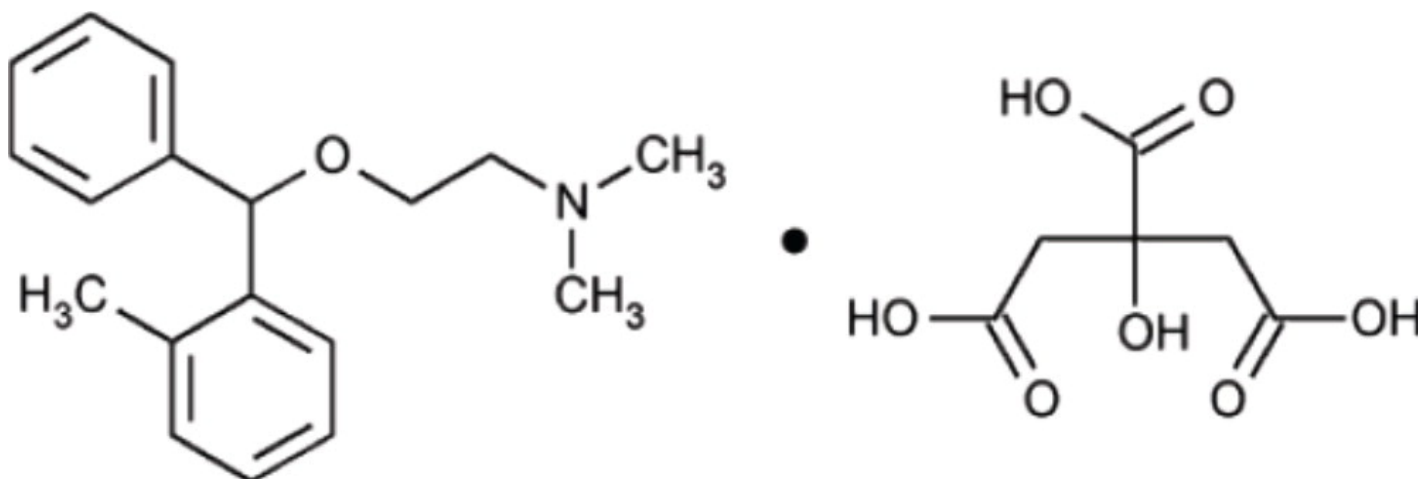
### **Orphenadrine Citrate Injection, USP** **(For Intravenous or Intramuscular Use)**

SAGENT®

R<sub>x</sub> 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. It has the following structural formula:



The empirical formula is  $C_{18}H_{23}NO \cdot C_6H_8O_7$ , representing a molecular weight of 461.50.

Orphenadrine Citrate Injection, USP contains 60 mg of orphenadrine citrate in aqueous solution in each vial. Orphenadrine Citrate Injection, USP also contains: sodium metabisulfite NF, 2.0 mg; sodium chloride USP, 5.8 mg; sodium hydroxide NF, to adjust pH; and water for injection USP, q.s. to 2 mL.

### **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 Injection is 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.

Orphenadrine citrate contains sodium metabisulfite, a sulfite that may cause allergic-type reactions including anaphylactic symptoms and life-threatening or less severe asthmatic episodes in certain susceptible people. The overall prevalence of sulfite sensitivity in the general population is unknown and probably low. Sulfite sensitivity is seen more frequently in asthmatic than nonasthmatic people.

## **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 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 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, 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.

Rare instances of anaphylactic reaction have been reported associated with the intramuscular injection of orphenadrine citrate.

**To report SUSPECTED ADVERSE REACTIONS, contact Sagent Pharmaceuticals, Inc. at 1-866-625-1618 or FDA at 1-800-FDA-1088 or [www.fda.gov/medwatch](http://www.fda.gov/medwatch).**

## **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**

INJECTION: Adults – One 2 mL vial (60 mg) intravenously or intramuscularly; may be repeated every 12 hours.

## **HOW SUPPLIED**

Orphenadrine Citrate Injection, USP is supplied as follows:

<b>NDC</b>	<b>Orphenadrine Citrate Injection, USP (30 mg per mL)</b>	<b>Package Factor</b>
25021-651-02	60 mg per 2 mL Single-Dose Vial	10 vials per carton

Orphenadrine Citrate Injection, USP is an aqueous solution.

## Storage Conditions

Store at 20° to 25°C (68° to 77°F); excursions permitted between 15° and 30°C (59° and 86°F). [See USP Controlled Room Temperature.]

**Protect from light.** Retain in carton until time of use.

Not to be sold in unbroken box.

Discard unused portion.

**Sterile, Nonpyrogenic, Preservative-free.**

**The container closure is not made with natural rubber latex.**

SAGENT®

Mfd. for SAGENT Pharmaceuticals

Schaumburg, IL 60195 (USA)

Made in India

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Revised: May 2021

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PACKAGE LABEL - PRINCIPAL DISPLAY PANEL - Vial Label

NDC 25021-651-02

Rx only

Orphenadrine Citrate Injection, USP

60 mg per 2 mL

(30 mg per mL)

For Intravenous or Intramuscular Use

2 mL Single-Dose Vial

NDC 25021-651-02 <sup>Rx only</sup>

**ORPHENADRINE  
CITRATE** INJECTION, USP

**60** mg per **2** mL  
(30 mg per mL)

For Intravenous or  
Intramuscular Use  
2 mL Single-Dose Vial

Mfd. for:  
SAGENT Pharmaceuticals  
Schaumburg, IL 60195 (USA)  
Made in India  
Code No.: GUJ/DRUGS/G/28/1609

(01)00325021651025

2079941

Lot:  
Exp.:

# ORPHENADRINE CITRATE

orphenadrine citrate injection, solution

## Product Information

<b>Product Type</b>	HUMAN PRESCRIPTION DRUG	<b>Item Code (Source)</b>	NDC:25021-651
<b>Route of Administration</b>	INTRAVENOUS, INTRAMUSCULAR		

## Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
orphenadrine citrate (UNII: X0A40N8I4S) (orphenadrine - UNII:AL805O9OG9)	orphenadrine citrate	30 mg in 1 mL

## Inactive Ingredients

Ingredient Name	Strength
sodium metabisulfite (UNII: 4VON5FNS3C)	1 mg in 1 mL
sodium chloride (UNII: 451W47IQ8X)	2.9 mg in 1 mL
sodium hydroxide (UNII: 55X04QC32I)	
water (UNII: 059QF0KO0R)	

## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:25021-651-02	10 in 1 CARTON	10/01/2011	
1		2 mL in 1 VIAL; Type 0: Not a Combination Product		

## Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA090585	10/01/2011	

**Labeler** - Sagent Pharmaceuticals (080579617)

Revised: 11/2023

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