ORPHENADRINE CITRATE- orphenadrine citrate injection
Hikma Pharmaceuticals USA Inc.

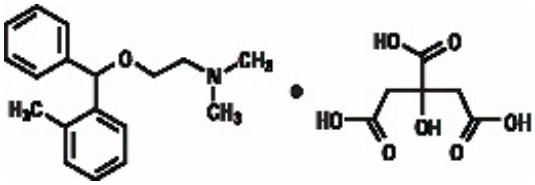
ORPHENADRINE CITRATE
INJECTION, USP

Rx only

DESCRIPTION

Orphenadrine citrate is the citrate salt of orphenadrine (±)-*N*,*N*-dimethyl-2-[(*o*-methyl-α-phenylbenzyl)oxy]-ethylamine citrate (1:1). It occurs as a white, crystalline powder having a bitter taste. It is practically odorless; sparingly soluble in water, slightly soluble in alcohol.

Each vial contains 60 mg of orphenadrine citrate in aqueous solution. Each vial also contains: sodium metabisulfite, 2 mg; sodium chloride, 5.8 mg; sodium hydroxide, to adjust pH; and water for injection, q.s. to 2 mL. The structural formula is:



$C_{18}H_{23}NO \cdot C_6H_8O_7$ MW 461.50

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 anticholinergic actions.

INDICATIONS AND USAGE

Orphenadrine citrate is indicated as an adjunct to rest, physical therapy, and other measures for the relief of discomfort associated with acute painful musculoskeletal 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 injection 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

Teratogenic Effects

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

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.

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

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 - One 2 mL vial (60 mg) intravenously or intramuscularly; may be repeated every 12 hours. Relief may be maintained by one (100 mg) orphenadrine citrate tablet twice daily.

Parenteral drug products should be inspected visually for particulate matter, whenever solution and container permit.

HOW SUPPLIED

Orphenadrine Citrate Injection, USP is supplied as follows:

Cartons of 10 (**NDC 0641-6182-10**) 2 mL vials, each vial containing 60 mg of orphenadrine citrate in aqueous solution.

Storage

Store at 20° to 25°C (68° to 77°F) [See USP Controlled Room Temperature].

Protect from light.

Single dose vial. Discard unused portion.

To report SUSPECTED ADVERSE REACTIONS, contact Hikma Pharmaceuticals USA Inc. at 1-877-845-0689, or the FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

For Product Inquiry call 1-877-845-0689.

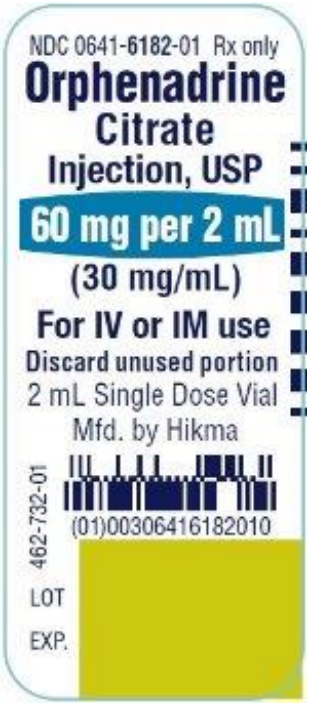
Manufactured by:
Hikma Pharmaceuticals USA Inc.
Berkeley Heights, NJ 07922

Revised December 2019

462-734-01

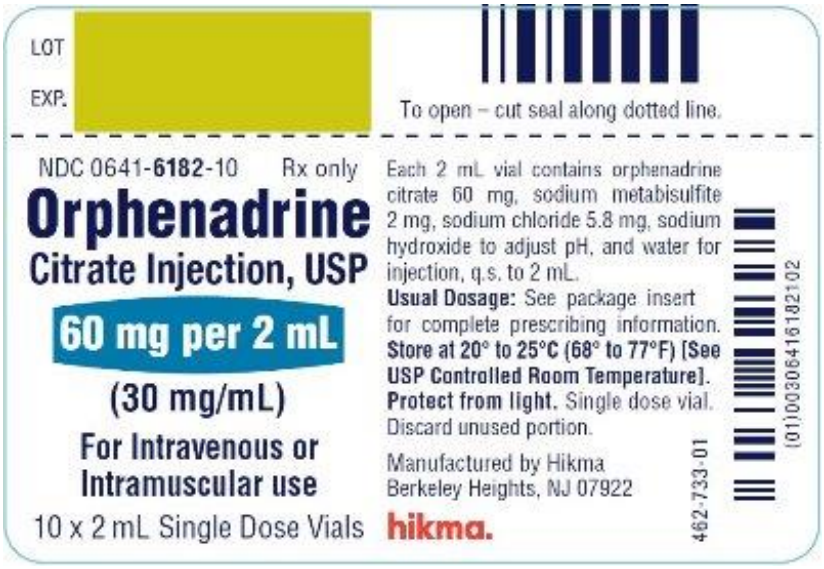
PRINCIPAL DISPLAY PANEL - CONTAINER

NDC 0641-**6182**-01 Rx only
Orphenadrine
Citrate
Injection, USP
60 mg per 2 mL
(30 mg/mL)
For IV or IM use
Discard unused portion
2 mL Single Dose Vial

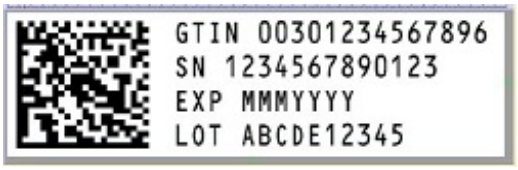


PRINCIPAL DISPLAY PANEL -SHELF PACK

NDC 0641-**6182**-10 Rx only
Orphenadrine
Citrate Injection, USP
60 mg per 2 mL
(30 mg/mL)
For Intravenous or
Intramuscular use
10 x 2 mL Single Dose Vials



SERIALIZATION IMAGE



ORPHENADRINE CITRATE

orphenadrine citrate injection

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:0641-6182
Route of Administration	INTRAMUSCULAR, INTRAVENOUS		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
ORPHENADRINE CITRATE (UNII: X0A40N8I4S) (ORPHENADRINE - UNII:AL805O9OG9)	ORPHENADRINE CITRATE	60 mg in 2 mL

Inactive Ingredients	
Ingredient Name	**Strength**
SODIUM CHLORIDE (UNII: 451W47IQ8X)	5.8 mg in 2 mL
SODIUM HYDROXIDE (UNII: 55X04QC32I)	
SODIUM METABISULFITE (UNII: 4VON5FNS3C)	2 mg in 2 mL
WATER (UNII: 059QF0KO0R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0641-6182-10	10 in 1 BOX	04/28/2003	
1	NDC:0641-6182-01	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	ANDA040463	04/28/2003	

Labeler - Hikma Pharmaceuticals USA Inc. (946499746)

Revised: 4/2022 Hikma Pharmaceuticals USA Inc.