ISOXSUPRINE HYDROCHLORIDE- isoxsuprine hydrochloride tablet
ECI Pharmaceuticals LLC

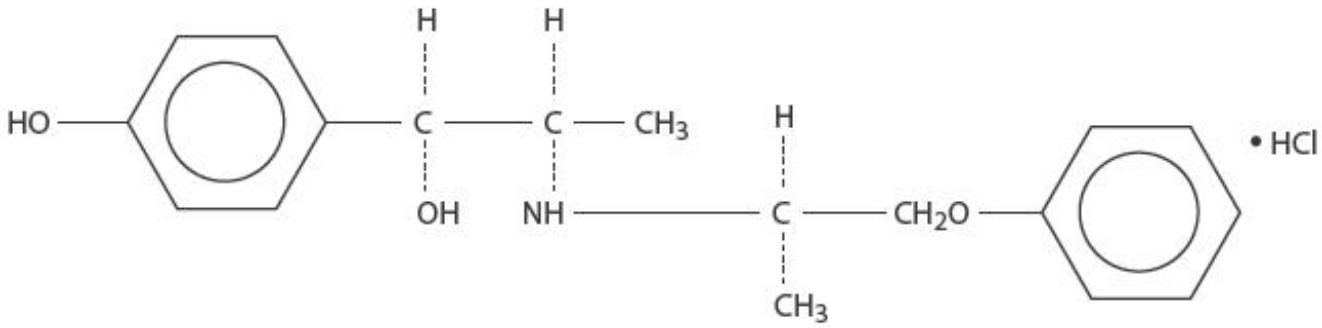
Disclaimer: This drug has not been found by FDA to be safe and effective, and this labeling has not been approved by FDA. For further information about unapproved drugs, click here.

Isoxsuprine Hydrochloride Tablets, USP

Rx Only

DESCRIPTION

Each tablet taken orally contains Isoxsuprine Hydrochloride, USP with the following chemical structure:



$C_{18}H_{23}NO_3 \cdot HCl$
p-Hydroxy-α[1-[(methyl-2-phenoxy-ethyl)amino]ethyl]benzyl alcohol hydrochloride.

Quantitative Ingredient Information: Each tablet taken orally contains 10 or 20 mg Isoxsuprine HCl
Pharmacological Class: Peripheral Vasodilator

INDICATIONS

Based on a review of this drug by the National Academy of Sciences-National Research and/or other information, the FDA has classified the indications as follows:

Possibly Effective

1. For the relief of symptoms associated with cerebrovascular insufficiency.
2. In peripheral vascular disease of arteriosclerosis obliterans, thromboangitis obliterans (Buerger's disease) and Raynaud's disease.

Final classification of the less-than-effective indications requires further investigation.

CONTRAINDICATIONS

There are no known contraindications to oral use when administered in recommended doses.

Isoxsuprine Hydrochloride, USP should not be given immediately postpartum or in the presence of arterial bleeding.

PRECAUTIONS

Pediatric Use

Safety and effectiveness in pediatric patients have not been established.

ADVERSE REACTIONS

On rare occasion oral administration of the drug has been associated in time with the occurrence of hypotension, tachycardia, chest pain, nausea, vomiting, dizziness, abdominal distress, and severe rash. If rash appears, the drug should be discontinued.

Although available evidence suggests a temporal association of these reactions with Isoxsuprine Hydrochloride, a causal relationship can be neither confirmed nor refuted.

Beta Adrenergic receptor stimulants such as Isoxsuprine Hydrochloride have been used to inhibit pre-term labor.

Maternal and fetal tachycardia may occur under such use. Hypocalcemia, hypoglycemia, hypotension and ileus have been reported to occur in infants whose mothers received Isoxsuprine Hydrochloride. Pulmonary edema has been reported in mothers treated with beta stimulants. Isoxsuprine Hydrochloride is neither approved nor recommended for use in the treatment of premature labor.

DOSAGE AND ADMINISTRATION

Oral: 10 to 20 mg, three or four times daily.

HOW SUPPLIED

Isoxsuprine HCl Tablets, USP 10 mg are white, round, biconvex tablets identified as "I10" debossed on one side and bisected on the other.

Bottle of 100	NDC 51293-606-01
Bottle of 1000	NDC 51293-606-10

Isoxsuprine HCl Tablets, USP 20 mg are white, round, biconvex tablets identified as "20" debossed on one side and bisected on the other.

Bottle of 100	NDC 51293-605-01
Bottle of 1000	NDC 51293-605-10

COMPOSITION

Isoxsuprine HCl Tablets, 10 mg and 20 mg. These tablets contain the following Inactive Ingredients: Corn Starch, Lactose Monohydrate, Magnesium Stearate (Vegetable), Microcrystalline Cellulose.

Manufactured By:
ECI Pharmaceuticals, LLC
Fort Lauderdale, FL 33309

Iss. 04/12

PRINCIPAL DISPLAY PANEL- 10 mg Bottle Label

ECI Pharmaceuticals

NDC 51293-606-01

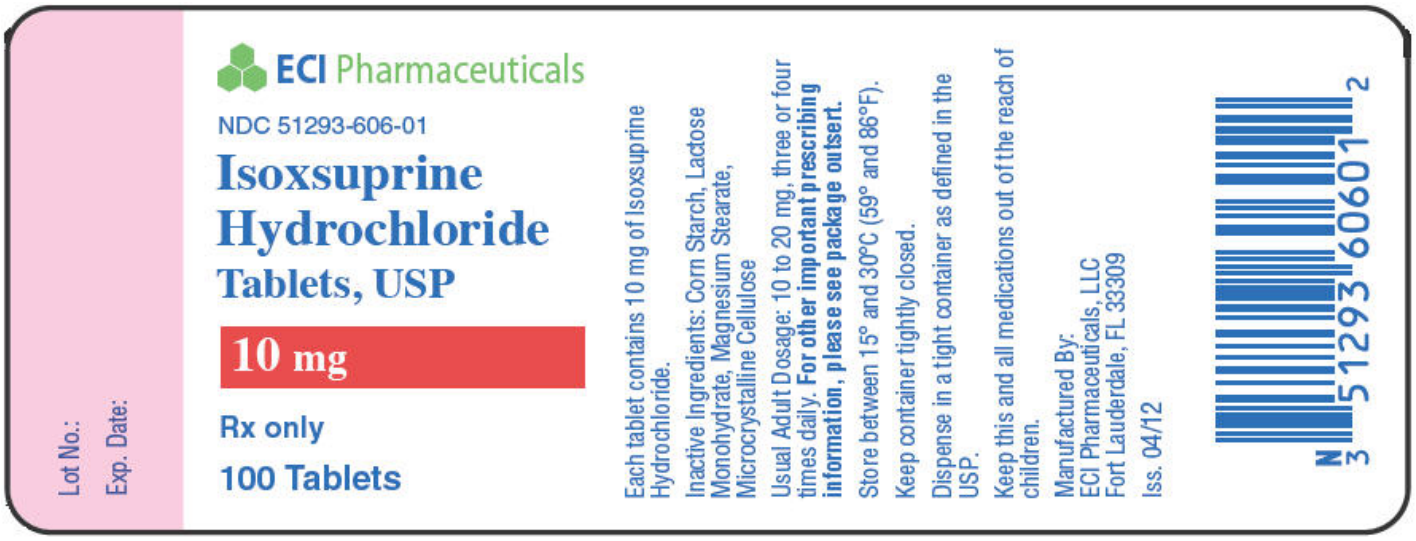
Isoxsuprine
Hydrochloride

Tablets, USP

10 mg

Rx only

100 Tablets



PRINCIPAL DISPLAY PANEL- 20 mg Bottle Label

ECI Pharmaceuticals

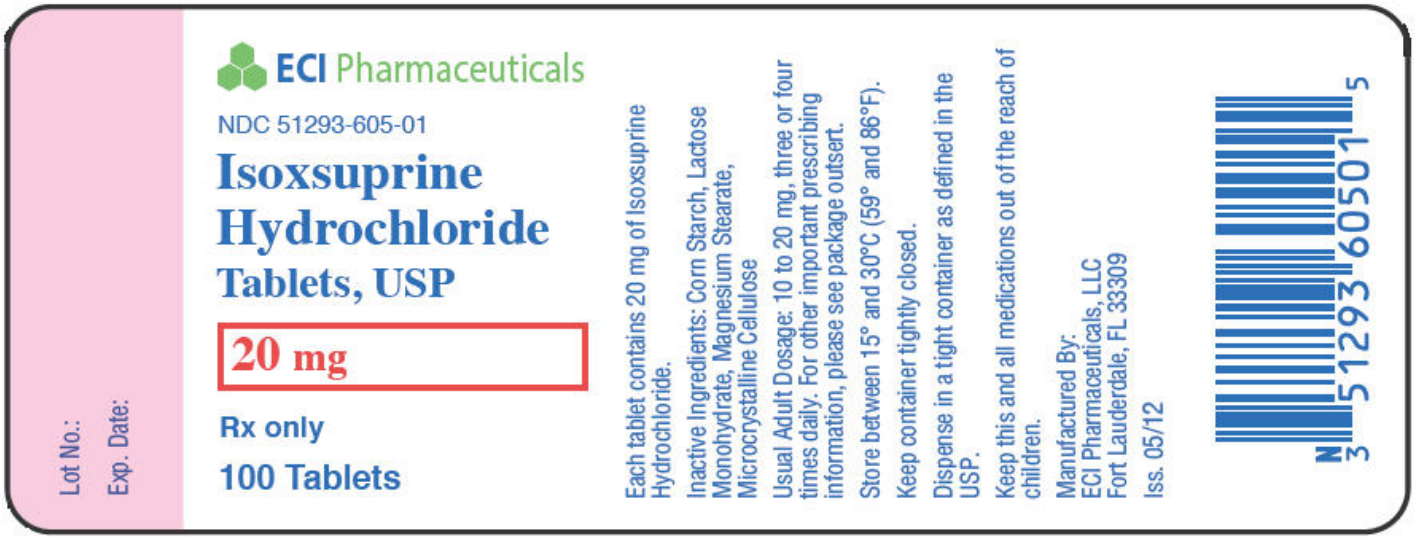
NDC 51293-605-01

Isoxsuprine
Hydrochloride
Tablets, USP

20 mg

Rx only

100 Tablets



ISOXSUPRINE HYDROCHLORIDE

isoxsuprine hydrochloride tablet

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:51293-606
Route of Administration	ORAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
isoxsuprine hydrochloride (UNII: V74TEQ36CO) (Isoxsuprine - UNII:R15UI3245N)	isoxsuprine hydrochloride	10 mg

Inactive Ingredients	
Ingredient Name	**Strength**
Lactose Monohydrate (UNII: EWQ57Q8I5X)	
Magnesium Stearate (UNII: 70097M6I30)	
Cellulose, Microcrystalline (UNII: OP1R32D61U)	
Starch, Corn (UNII: O8232NY3SJ)	

Product Characteristics			
Color	WHITE	**Score**	2 pieces
Shape	ROUND	**Size**	8mm
Flavor		**Imprint Code**	I10
Contains			

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:51293-606-01	100 in 1 BOTTLE; Type 0: Not a Combination Product	08/23/2011	
2	NDC:51293-606-10	1000 in 1 BOTTLE; Type 0: Not a Combination Product	08/23/2011	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
UNAPPROVED DRUG OTHER		06/02/2011	

ISOXSUPRINE HYDROCHLORIDE

isoxsuprine hydrochloride tablet

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:51293-605
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
isoxsuprine hydrochloride (UNII: V74TEQ36CO) (Isoxsuprine - UNII:R15UI3245N)	isoxsuprine hydrochloride	20 mg

Inactive Ingredients

Ingredient Name	Strength
Lactose Monohydrate (UNII: EWQ57Q8I5X)	
Magnesium Stearate (UNII: 70097M6I30)	
Cellulose, Microcrystalline (UNII: OP1R32D61U)	
Starch, Corn (UNII: O8232NY3SJ)	

Product Characteristics

Color	WHITE	**Score**	2 pieces
Shape	ROUND	**Size**	8mm
Flavor		**Imprint Code**	20
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:51293-605-01	100 in 1 BOTTLE; Type 0: Not a Combination Product	08/23/2011	
2	NDC:51293-605-10	1000 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	08/23/2011	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
UNAPPROVED DRUG OTHER		08/23/2011	

Labeler - ECI Pharmaceuticals LLC (962476029)

Revised: 12/2018 ECI Pharmaceuticals LLC