ISOXSUPRINE HYDROCHLORIDE- isoxsuprine hydrochloride tablet
Vista Pharmaceuticals, Inc.

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.

ISOXSUPRINEHYDROCHLORIDE TABLETS, USP

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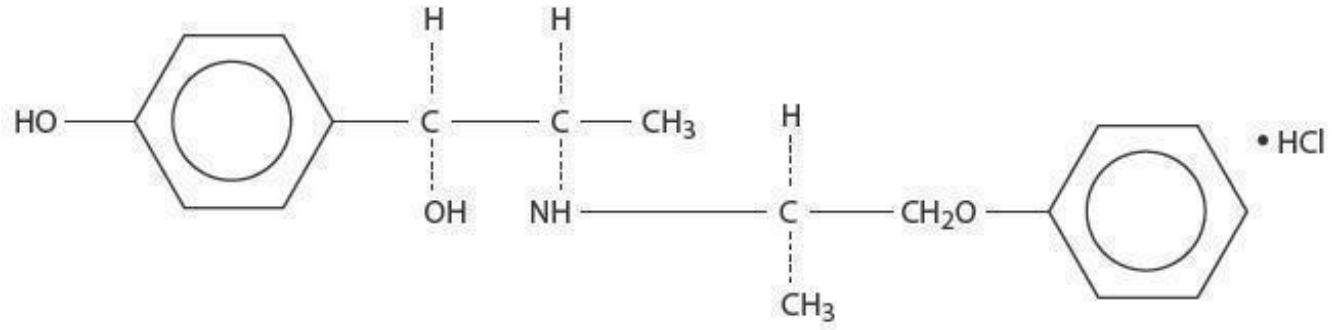
CAUTION: Federal Law prohibits dispensing without prescription

DESCRIPTION

Isoxsuprine HCI occurs as a white odorless, crystalline powder, having a bitter taste, It has a following structural formula



INDICATIONS

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

Possibly Effective :
1. For the relief of symptoms associated with cerebral vascular 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.

COMPOSITION

Each tablet contains lsoxsuprine HCI 20 mg.

These tablets contain the following inactive ingredients: dibasic calcium phosphate (anhydrous), lactose, magnesium stearate. microcrystalline cellulose, povidone k30, and sodium starch glycolate.

DOSAGEANDADMINISTRATION

Oral:10 to 20 mg three or four times daily

CONTRAINDICATIONS AND CAUTIONS

Oral

There are no known contraindications to oral use when administered in recommended doses. Should not be given immediately postpartum or in the presence of arterial bleeding.

ADVERSE REACTIONS

On rare occasion, oral administration of the drug has been associated in time with the occurrences 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, a casual relationship can be neither confirmed nor refuted.

β-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. Pulmonary edema has been reported in mothers treated with β-stimulants. Isoxsuprine HCl tablets, USP is neither approved nor recommended for use in the treatment of premature labor.

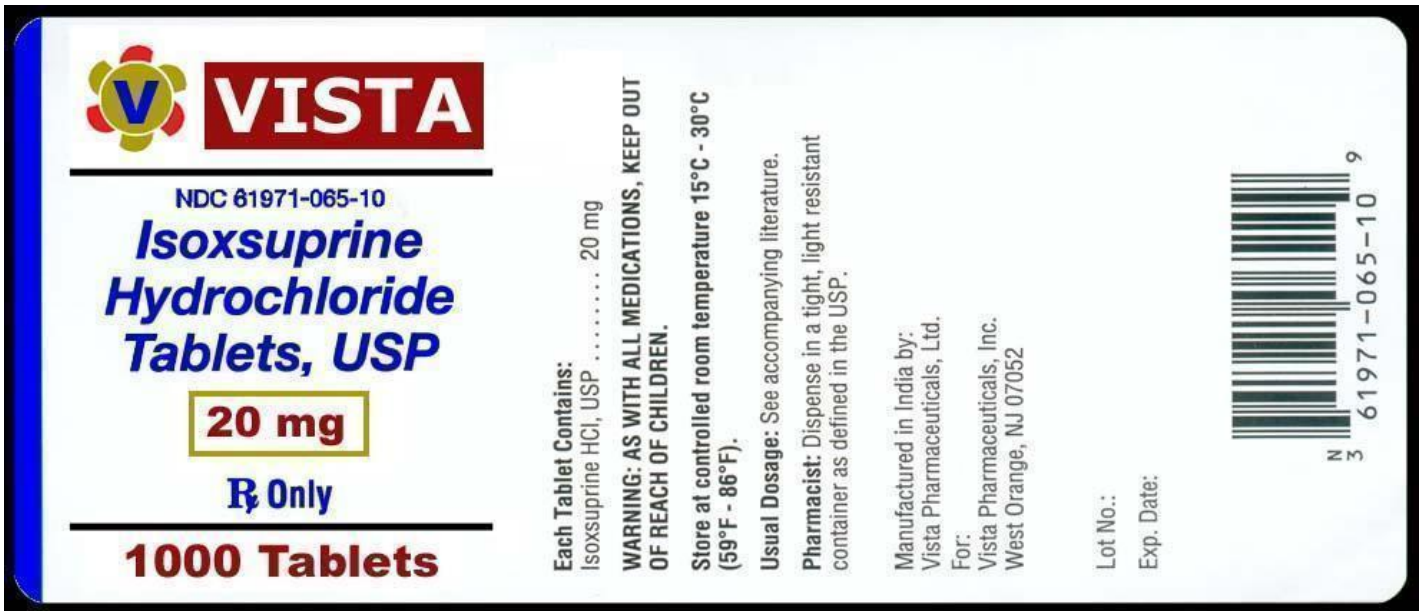
HOW SUPPLIED

Isoxsuprine HCI tablets, USP are supplied in HDPE bottles.

20 mg Bottles of 1,000's: NDC61971-065-10

Manufactured in India by
Vista Pharmaceuticals, Limited.

For
Vista Pharmaceuticals, Inc.
Revised:07/2017



ISOXSUPRINE HYDROCHLORIDE

isoxsuprine hydrochloride tablet

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:61971-065
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 (UNII: J2B2A4N98G)	
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
CALCIUM PHOSPHATE, DIBASIC, ANHYDROUS (UNII: L11K75P92J)	
POVIDONE K30 (UNII: U725QWY32X)	
SODIUM STARCH GLYCOLATE TYPE A POTATO (UNII: 5856J3G2A2)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	

Product Characteristics

Color	white	**Score**	2 pieces
Shape	ROUND	**Size**	10mm
Flavor		**Imprint Code**	20;VISTA065
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:61971-065-10	1000 in 1 BOTTLE; Type 0: Not a Combination Product	09/19/1997	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
unapproved drug other		09/19/1997	

Labeler - Vista Pharmaceuticals, Inc. (943932806)

Establishment

Name	Address	ID/FEI	Business Operations
Vista Pharmaceuticals, Limited.		916648541	manufacture(61971-065) , analysis(61971-065)

Revised: 7/2017 Vista Pharmaceuticals, Inc.