

ISOXSUPRINE HYDROCHLORIDE - isoxsuprine hydrochloride tablet
Vista Pharmaceuticals, Inc.

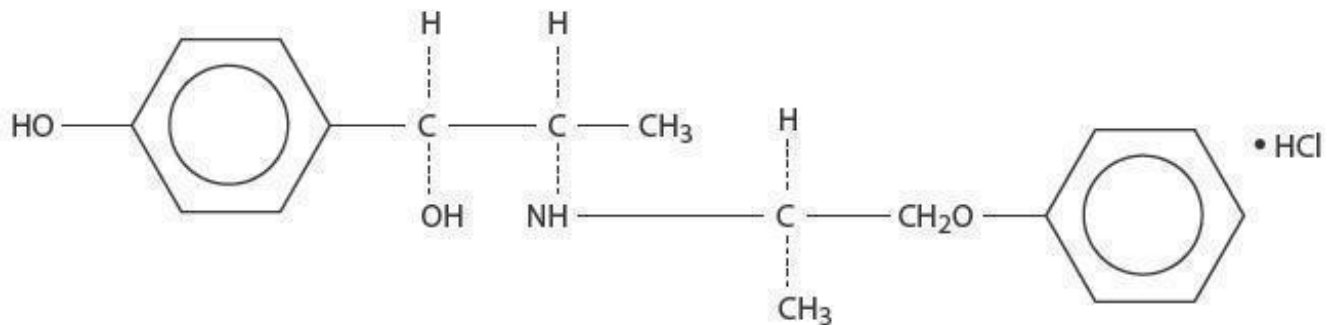
Disclaimer: This drug has not been found by FDA to be safe and effective, and this labeling has not been approved by FDA. For further information about unapproved drugs, click here.

ISOXSUPRINE HYDROCHLORIDE TABLETS, USP

CAUTION: Federal Law prohibits dispensing without prescription

DESCRIPTION

Isoxsuprine HCl 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 Isoxsuprine HCl 20 mg.

CONTRAINDICATIONS AND CAUTIONS

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 occasions oral administration of the drug has been associated in time with the occurrences of hypotension, tachycardia, 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 refused.

DOSAGE AND ADMINISTRATION

10 to 20mg three or four times daily

HOW SUPPLIED

Isoxsuprine HCl 20mg tablets are supplied in HDPE containers of 1,000's

Manufactured in India by
Vista Pharmaceuticals, Limited.

VISTA

NDC 61971-065-10

Isoxsuprine Hydrochloride Tablets, USP

20 mg

Rx Only

1000 Tablets

Each Tablet Contains:
Isoxsuprine HCl, USP 20 mg

WARNING: AS WITH ALL MEDICATIONS, KEEP OUT OF REACH OF CHILDREN.

Store at controlled room temperature 15°C - 30°C (59°F - 86°F).

Usual Dosage: See accompanying literature.

Pharmacist: Dispense in a tight, light resistant container as defined in the USP.

Manufactured in India by:
Vista Pharmaceuticals, Ltd.

For:
Vista Pharmaceuticals, Inc.
West Orange, NJ 07052

Lot No.:
Exp. Date:

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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:R15UIB245N)	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		

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: 12/2012

Vista Pharmaceuticals, Inc.