

NASAL DECONGESTANT- oxymetazoline hydrochloride solution/ drops
THE IBN SINA PHARMACEUTICAL INDUSTRY LTD.

Disclaimer: Most OTC drugs are not reviewed and approved by FDA, however they may be marketed if they comply with applicable regulations and policies. FDA has not evaluated whether this product complies.

IBN OXYMETAZOLINE NASAL SOLUTION

Drug Facts

Active ingredient

Oxymetazoline hydrochloride 0.05%

Purpose

Nasal decongestant

Uses

- temporarily relieves nasal congestion due to:
- common cold
- hay fever
- upper respiratory allergies

Warnings

Ask a doctor before use if you have

- heart disease
- high blood pressure
- thyroid disease
- diabetes
- trouble urinating due to an enlarged prostate gland

When using this product

- **do not exceed recommended dosage**
- do not use for more than 3 days. Use only as directed. Frequent or prolonged use may cause nasal congestion to recur or worsen
- it may cause temporary discomfort such as burning, stinging, sneezing or an increase in nasal discharge
- use of this container by more than one person may spread infection

Stop use and ask a doctor if symptoms persist

If pregnant or breast-feeding, ask a health professional before use.

Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center (1-800-222-1222) right away.

Directions

- Adults and children 6 to under 12 years of age (with adult supervision): 2 or 3 drops in each nostril not more often than every 10-12 hours. Do not exceed 2 doses in any 24-hour period.
- Children under 6 years of age: consult a doctor.

Other information

- store between 15° to 30°C (59° to 86°F)
- **TAMPER EVIDENT: DO NOT USE IF SAFETY SEAL ON BOTTLE OR DROPPER TIP IS LOOSE, BROKEN OR MISSING**

Inactive ingredients

benzalkonium chloride, edetate disodium, glycerin, potassium phosphate monobasic, sodium chloride, sodium phosphate dibasic dihydrate, water.

Questions?

1-833-IBN-SINA (1-833-426-7462)

Manufactured by:

The **IBN SINA** Pharmaceutical Industry Ltd.

Holding # A-80, Ward # 9, Shafipur, Kaliakoir,

Gazipur-1751, Bangladesh

www.ibnsinapharma.com

Product of Bangladesh

NDC 72103-333-15

NASAL DECONGESTANT

Oxymetazoline HCL 0.05% Nasal Solution

Helps relieve congestion

0.34 FL OZ (10 mL)



NASAL DECONGESTANT			
oxymetazoline hydrochloride solution/ drops			
Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:72103-333
Route of Administration	NASAL		
Active Ingredient/Active Moiety			
Ingredient Name		Basis of Strength	Strength
OXYMETAZOLINE HYDROCHLORIDE (UNII: K89MJ0S5VY) (OXYMETAZOLINE - UNII:8VLN5B44ZY)		OXYMETAZOLINE HYDROCHLORIDE	0.05 g in 100 mL
Inactive Ingredients			
Ingredient Name			Strength

BENZALKONIUM CHLORIDE (UNII: F5UM2KM3W7)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	
SODIUM CHLORIDE (UNII: 451W47IQ8X)	
SODIUM PHOSPHATE, DIBASIC, DIHYDRATE (UNII: 94255I6E2T)	
POTASSIUM PHOSPHATE, MONOBASIC (UNII: 4J9FJ0HL51)	
GLYCERIN (UNII: PDC6A3C0OX)	
WATER (UNII: 059QF0K00R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:72103-333-15	1 in 1 CARTON	03/12/2019	
1		10 mL in 1 BOTTLE, DROPPER; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part341	03/12/2019	

Labeler - THE IBN SINA PHARMACEUTICAL INDUSTRY LTD. (731557752)

Establishment

Name	Address	ID/FEI	Business Operations
THE IBN SINA PHARMACEUTICAL INDUSTRY LTD.		731557752	manufacture(72103-333)

Revised: 3/2019

THE IBN SINA PHARMACEUTICAL INDUSTRY LTD.