PRIVINE- naphazoline hydrochloride spray Insight Pharmaceuticals

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.

Privine[®] nas al s pray

Drug Facts

Active ingredient (per spray)

Naphazoline HCl, USP 0.05%

Purpose

Nasal decongestant

Uses

for temporary relief of nasal congestion

- due to a cold
- due to hay fever or other upper respiratory allergies
- shrinks swollen membranes so you can breathe more freely

Warnings

Ask a doctor before use if you have

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

When using this product

- do not exceed recommended dos age
- temporary discomfort such as burning, stinging, sneezing, or an increase in nasal discharge may occur
- do not use for more than 3 days. Frequent or prolonged use may cause nasal congestion to come back or get worse.
- use only as directed

Stop use and ask a doctor if symptoms persist

The use of this container by more than one person may spread infection

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 right away.

Directions

- adults and children 12 years of age and over: 1 or 2 sprays in each nostril not more often than every 6 hours.
- children under 12 years of age: consult a doctor.

Other information

store at room temperature 20°–25°C (68°–77°F).

Inactive Ingredients

benzalkonium chloride, dibasic sodium phosphate, disodium edetate, monobasic sodium phosphate, purified water and sodium chloride.

Questions

Call 1-800-344-7239 or write to Consumer Affairs.

Distributed by:

INSIGHT Pharmaceuticals Corp.

Langhorne, PA 19047-1749

PRINCIPAL DISPLAY PANEL - 20 mL spray label

69853C LF-572

FAST RELIEF OF STUFFY NOSE

Privine®
nas al spray
naphazoline HCl, USP
Nas al Decongestant

Do not use if the plastic band on the bottle cap is missing or damaged. Store between 20°-25°C (68°-77°F).

0.66 fl oz (20 mL)



Indications: For the temporary relief of recal congection due to the common cold, they tower or other upper respiratory alwayses.

Brachimes Adults and children 12 years of age and over 5 or 2 spaces to each easter from more other than every 6 hours. Do not got to children under 12 years of age treates descared by a doctor. Advise largeodesist 0.02% rephasible HCL USP.

Warning: Do not stored recommended desage. This product may cause temporary disconting such as burning, storying, securing, or an increase in meast destange. To not use this product for more than 3 days. Use only as directed Frequent or producing or an increase quasar seas of congestion to future or woman. If symptoms period, consult a doctor. Do not use this product if you have heart desages, they blood pressure, through discase, disbates, or difficulty in unfrathon due to enterportment of the procedule gland unlikes discased by a doctor it pregnant are breast-feeting, and a health profused indication they are feeting to the continuous of the procedule gland unlikes discased. The use of this continuous by more than product of indication may prove dischools feeting and magnitude than the procedule of indication and feeting the contact a Posson Control Contact night away.

Discharded by 1850AT Palmar were to Commence Affairs.

PRINCIPAL DISPLAY PANEL - 20 mL spray carton

Fast relief of stuffy nose

Privine®
nas al spray
naphazoline HCl, USP
Nas al Decongestant

Important:

Do not use if the plastic band on the bottle cap is missing or damaged.

0.66 fl oz (20mL)



PRIVINE

naphazoline hydrochloride spray

Product Information

Product Type HUMAN OTC DRUG Item Code (Source) NDC:63736-662

Route of Administration NASAL

Active Ingredient/Active Moiety

Ingredient NameBasis of StrengthStrengthNaphazoline Hydrochloride (UNII: MZ1131787D) (Naphazoline - UNII:H231GF11BV)Naphazoline0.1 mL in 20 mL

Inactive Ingredients

Ingredient Name	Strength		
benzalkonium chloride (UNII: F5UM2KM3W7)			
sodium phosphate, dibasic (UNII: GR686LBA74)			
edetate disodium (UNII: 7FLD91C86K)			
sodium phosphate, monobasic (UNII: 3980 JIH2SW)			
water (UNII: 059QF0KO0R)			

sodium chloride (UNII: 451W47IQ8X)						
Product Characteristics						
Color	WHITE (clear)	Score				
Shape		Size				
Flavor		Imprint Code				
Contains						

P	Packaging						
#	Item Code	Package Description	Marketing Start Date	Marketing End Date			
1	NDC:63736-662-02	1 in 1 BOX					
1		20 mL in 1 BOTTLE					

Marketing Information						
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date			
OTC monograph final	part341	07/16/2009				

Labeler - Insight Pharmaceuticals (176792315)

Revised: 7/2009 Insight Pharmaceuticals