# PRIVINE- naphazoline hydrochloride suspension/ drops Insight Pharmaceuticals LLC

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.

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Privine<sup>®</sup> nas al drops

Drug Facts

## Active ingredient (per drop)

Naphazoline HCl, USP 0.05%

#### **Purpose**

Nasal decongestant

#### Uses

for the temporary relief of nasal congestion

- due to a cold
- due to hay fever or other upper respiratory allergies
- helps clear nasal passages; shrinks swollen membranes
- temporarily restores freer breathing through the nose

#### **Warnings**

**Do not use** this product in children under 12 years of age because it may cause sedation if swallowed.

## 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 dosage
- temporary discomfort such as burning, stinging, sneezing, or an increase in nasal discharge may occur
- do not use for more than 3 days. Use only as directed. Frequent or prolonged use may cause nasal congestion to come back or get worse.
- the use of this container or dropper 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 right away.

### **Directions**

- adults and children 12 years of age and over: 1 or 2 drops 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).
- Keep carton for full drug facts.

## **Inactive Ingredients**

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

### **Questions**

Call 1-800-344-7239

Distributed by:

**INSIGHT Pharmaceuticals Corp.** 

Langhorne, PA 19047-1749

## PRINCIPAL DISPLAY PANEL - 25 mL Drops Carton

Fast relief of stuffy nose

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

**Important:** Do not use if seal under bottle cap imprinted with "Sealed for your protection" is missing or broken.

0.83 fl oz (25mL)



#### **PRIVINE**

naphazoline hydrochloride suspension/ drops

#### **Product Information**

Product Type HUMAN OTC DRUG Item Code (Source) NDC:63736-663

Route of Administration NASAL

#### **Active Ingredient/Active Moiety**

Ingredient Name Basis of Strength Strength

Naphazoline Hydrochloride (UNII: MZ1131787D) (Naphazoline - UNII:H231GF11BV) Naphazoline Hydrochloride | 0.125 mL in 25 mL

#### **Inactive Ingredients**

**Ingredient Name** 

Strength

benzalkonium chloride (UNII: F5UM2KM3W7)	
sodium phosphate, dibasic (UNII: GR686LBA74)	
edetate disodium (UNII: 7FLD91C86K)	
sodium phosphate, monobasic (UNII: 3980JIH2SW)	
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:63736-663-01	1 in 1 BOX				
1		25 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 LLC (176792315)

Revised: 1/2011 Insight Pharmaceuticals LLC