

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[®]
nasal spray

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 dosage**
- 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®

nasal spray

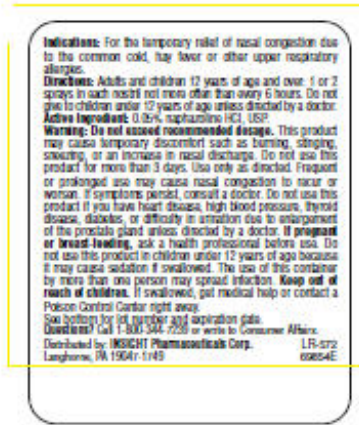
naphazoline HCl, USP

Nasal 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)



PRINCIPAL DISPLAY PANEL - 20 mL spray carton

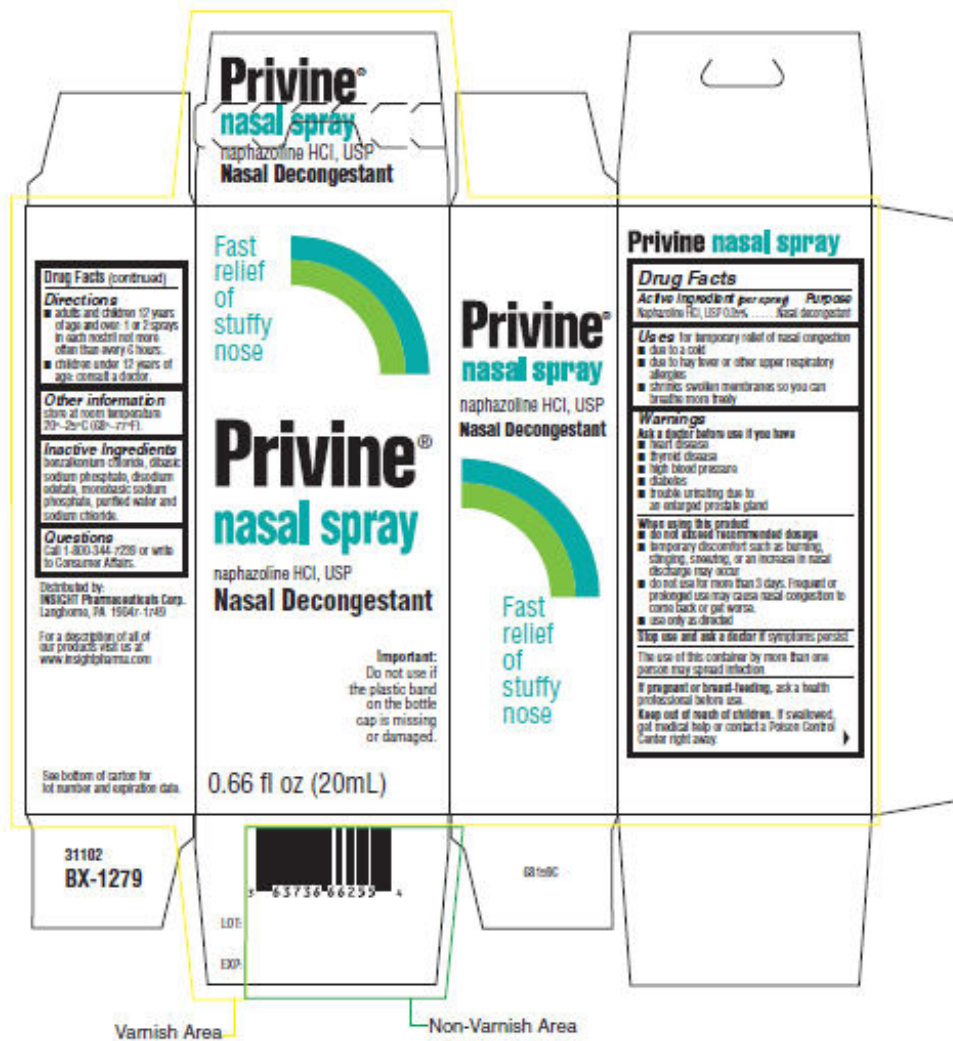
Fast
relief
of
stuffy
nose

Privine®
nasal spray
naphazoline HCl, USP
Nasal 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 Name	Basis of Strength	Strength
Naphazoline Hydrochloride (UNII: MZ1131787D) (Naphazoline - UNII:H231GF11BV)	Naphazoline	0.1 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: 3980JIH2SW)	
water (UNII: 059QF0K0OR)	

sodium chloride (UNII: 451W47IQ8X)

Product Characteristics

Color	WHITE (clear)	Score	
Shape		Size	
Flavor		Imprint Code	
Contains			

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