

CAREONE COLD AND SINUS- phenylephrine hydrochloride solution/ drops
American Sales Company

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.

American Sales Company Cold & Sinus Nose Drops Drug Facts

Active ingredient

Phenylephrine hydrochloride 1.0%

Purpose

Nasal decongestant

Uses

- temporarily relieves nasal congestion due to:
- common cold
- hay fever
- upper respiratory allergies
- temporarily relieves sinus congestion and pressure
- shrinks swollen membranes so you can breathe more freely
- temporarily restores freer breathing through the nose

Warnings

Do not use

if you have ever had an allergic reaction to this product or any of its ingredients

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 use more than directed**
- do not use for more than 3 days. Use only as directed. Frequent or prolonged use may cause nasal congestion to recur or worsen.
- temporary discomfort such as burning, stinging, sneezing, or an increase in nasal discharge may occur
- 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 right away (1-800-222-1222).

Directions

- use only as directed
- adults and children 12 years of age and older: 2 or 3 drops in each nostril not more often than every 4 hours
- children under 12 years of age: ask a doctor

Other information

- store at 20-25°C (68-77°F)
- Protect from light. Store in outer carton until contents used.

Inactive ingredients

anhydrous citric acid, benzalkonium chloride solution, purified water, sodium chloride, sodium citrate

Questions or comments?

1-800-719-9260

Principal Display Panel

Compare to the active ingredient in Neo-Synephrine® Extra Strength

COLD & SINUS NOSE DROPS

Phenylephrine HCl 1.0%

Nasal Decongestant

4hr

Extra Strength

Easy To Use & Dispense

Relieves:

Nasal Congestion

Sinus Congestion

Sinus Pressure

Non-drowsy

Gluten Free

OUR PHARMACISTS RECOMMEND

1 FL OZ (30mL)



CAREONE COLD AND SINUS

phenylephrine hydrochloride solution/ drops

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:41520-831
Route of Administration	NASAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
PHENYLEPHRINE HYDROCHLORIDE (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII:1WS297W6MV)	PHENYLEPHRINE HYDROCHLORIDE	1 g in 100 mL

Inactive Ingredients

Ingredient Name	Strength
BENZALKONIUM CHLORIDE (UNII: F5UM2KM3W7)	
ANHYDROUS CITRIC ACID (UNII: XF417D3PSL)	
WATER (UNII: 059QF0KO0R)	
SODIUM CHLORIDE (UNII: 451W47IQ8X)	
SODIUM CITRATE (UNII: 1Q73Q2JULR)	

Product Characteristics

Color	YELLOW (Clear to slightly yellow)	Score	
Shape		Size	
Flavor		Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:41520-831-10	1 in 1 CARTON	10/20/2016	
1		30 mL in 1 BOTTLE; 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	10/20/2016	

Labeler - American Sales Company (809183973)

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American Sales Company