CAREONE FAST ACTING NASAL- phenylephrine hydrochloride spray 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 Fast Acting Nasal Spray Drug Facts

Active ingredient

Phenylephrine hydrochloride 1%

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
- diabetes
- thyroid disease
- high blood pressure
- 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. Frequent or prolonged use may cause nasal congestion to come back or get worse.
- use only as directed
- 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

- adults and children 12 years and over: 2 or 3 sprays in each nostril not more often than every 4 hours
- children under 12 years: ask a doctor
- Use instructions: with head in a normal, upright position, put atomizer tip into nostril. Squeeze bottle with firm, quick pressure while inhaling. Wipe nozzle clean after each use.

Other information

store at 20°-25°C (68°-77°F)

Inactive ingredients

benzalkonium chloride, benzyl alcohol, boric acid, purified water, sodium borate

Questions or comments?

1-800-719-9260

Principal Display Panel

Compare to the active ingredient in 4-Way® Fast Acting Nasal Spray

FAST ACTING NASAL SPRAY

Phenylephrine Hydrochloride 1 %

Nasal Decongestant

4hr

Relieves:

Nasal Congestion

Swollen Nasal Membranes

Sinus Congestion

Sinus Pressure

Gluten Free

OUR PHARMACISTS RECOMMEND

1 FL OZ (30mL)



CAREONE FAST ACTING NASAL

phenylephrine hydrochloride spray

Product Information

Product Type HUMAN OTC DRUG Item Code (Source) NDC:41520-729

Active Ingredient/Active Moiety						
Ingredient Name	Basis of Strength	Strength				
PHENYLEPHRINE HYDROCHLORIDE (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII: 1W5297W6MV)	PHENYLEPHRINE HYDROCHLORIDE	1 g in 100 mL				

Inactive Ingredients			
Ingredient Name	Strength		
BENZALKONIUM CHLORIDE (UNII: F5UM2KM3W7)			
BENZYL ALCOHOL (UNII: LKG8494WBH)			
BORIC ACID (UNII: R57ZHV85D4)			
SODIUM BORATE (UNII: 91MBZ8H3QO)			
WATER (UNII: 059QF0KO0R)			

P	Packaging					
#	Item Code	Package Description	Marketing Start Date	Marketing End Date		
1	NDC:41520-729- 10	1 in 1 CARTON	11/30/2016			
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	11/30/2016		

Labeler - American Sales Company (809183973)

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