NASAL DECONGESTANT RHINALL- phenylephrine hydrochloride 0.25 spray
Product Quest Mfg.

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.

Frug Facts

Active ingredient **Purpose**

Phenylephrine HCl 0.25%.....Nasal decongestan

Uses

Temporarly relieves nasal congestion due to • common cold • hay fever or other respiratory allergies associated with sinusitis • stuffy nose
Helps clear nasal passages; shrinks swollen membranes.
Temporarily restores freer breathing through the nose.
Helps decongest sinus openings and passages; temporarily relieves sinus congestion.

Warnings

Do not exceed recommended dosage

Ask a doctor before use if you have: • heart disease • high blood pressure • diabetes• thyroid disease • difficulty in urination due to enlargement of the prostate gland

When using this product temporary discomfort may occur such as: • burning • stinging • sneezing • increase in nasal discharge • Use by more than one person may spread infection

Stop use and ask doctor if symptoms persist.

Do not use for more than 3 days. Use only as directed. Frequent or prolonged use may cause nasal congestion to recur or worsen.
If pregnant or breastfeeding, ask a health care professional before use.

KEEP OUT OF THE REACH OF CHILDREN. If swallowed, get medical help or contact a Poison Control Center immediately.

Directions

Adults and children 12 years of age and over: 2 or 3 drops in each nostril not more often than every 4 hours. **Children under 12 years of age**: ask a doctor.

Inactive ingredients

Benzalkonium Chloride, Chlorobutanol Hemihydrate, Disodium EDTA, Polysorbate, Sodium Bisulfite, Sodium Chloride, Sorbitol, Water.

NASAL DECONGESTANT RHINALL

phenylephrine hydrochloride 0.25 spray

Product Information

Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:64048-5000
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
PHENYLEPHRINE HYDROCHLORIDE (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII:1WS297W6MV)	PHENYLEPHRINE	0.25 g in 100 mL

Inactive Ingredients

Ingredient Name	Strength
BENZALKONIUM CHLORIDE (UNII: F5UM2KM3W7)	
CHLOROBUTANOL HEMIHYDRATE (UNII: 3X4P6271OX)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	
POLYSORBATE 20 (UNII: 7T1F30V5YH)	
SODIUM BISULFITE (UNII: TZX5469Z6I)	

SODIUM CHLORIDE (UNII: 451W47IQ8X)	
SORBITOL (UNII: 506T60A25R)	
WATER (UNII: 059QF0KO0R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:64048-5000-1	1 in 1 CARTON	01/15/2010	
1		40 mL in 1 TUBE; 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	01/15/2010	

Labeler - Product Quest Mfg. (927768135)

Establishment

Name	Address	ID/FEI	Business Operations
Product Quest Mfg.		927768135	manufacture(64048-5000) , label(64048-5000)

Revised: 3/2018 Product Quest Mfg.