LITTLE REMEDIES DECONGESTANT NASAL DROPS- phenylephrine hydrochloride liquid Medtech Products Inc.

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.

Little Remedies Decongestant Nose Drops

${\bf LITTLE\ REMEDIES\ DECONGESTANT\ NOSE\ DROPS-\ phenylephrine\ hydrochloride\ liquid}$

Little Decongestant Drops

Drug Facts

Active ingredient

Phenylephrine Hydrochloride 0.125%

Purpose

Nasal decongestant

Uses

- temporarily relieves nasal congestion due to common cold, hay fever or other upper respiratory allergies
- helps clear nasal passages; shrinks swollen membranes
- temporarily restores freer breathing through the nose
- helps decongest sinus openings and passages; temporarily relieves sinus congestion and pressure

Warnings

Ask a doctor before use if the child has

- heart disease
- high blood pressure
- thyroid disease
- diabetes

When using this product

- temporary discomfort such as burning, stinging, sneezing or an increase in nasal discharge may occur
- the use of this dispenser by more than one person may spread infection
- do not use more than 3 days. Ues only as directed. Frequest or prolonged use may cause nasal congestion to revcur or worsen.

Stop use and ask a doctor if

Keep out of reach of children.

In case of overdose, get medical help or contact a Poison Control Center (1-800-222-1222) right away.

Directions

(nasal use only)

- **Children 2 to under 6 years (with adult supervision):** 2 to 3 drops in each nostril, not more often than every 4 hours. **Use only recommended amount.**
- **Children under 2 years of age:** Consult a doctor

Other information

- Do not use if solution is brown or contains a precipitate.
- Protect from light.
- Store at 20-25°C (68-77°F).
- See bottle or box for lot number and expiration date.

Inactive ingredients

benzalkonium chloride, glycerin, polyethylene glycol, potassium phosphate monobasic, purified water, sodium edta, sodium phosphate dibasic

Questions?

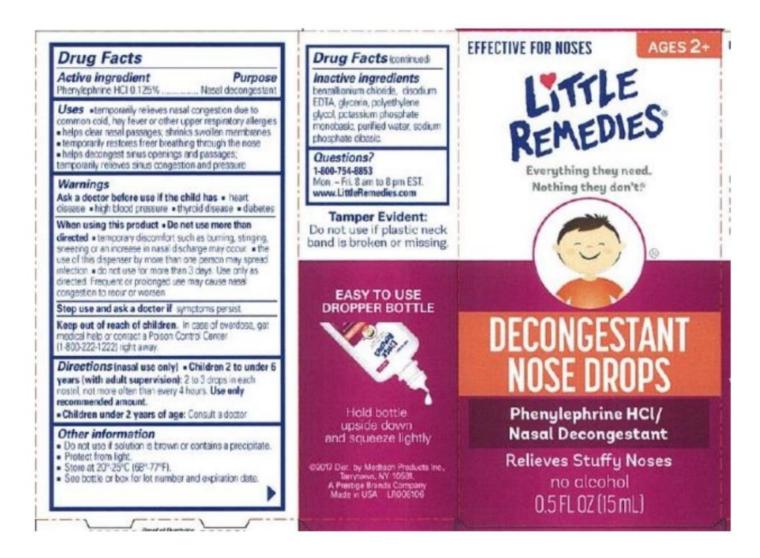
1-800-754-8853 Mon. – Fri. 8 am to 8 pm EST. www.LittleRemedies.com

PRINCIPAL DISPLAY PANEL

Little Remedies®

DECONGESTANT NOSE DROPS Phenylephrine HCl/Nasal Decongestant

0.5 FL OZ (15 mL)



LITTLE REMEDIES DECONGESTANT NASAL DROPS

phenylephrine hydrochloride liquid

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:63029-403
Route of Administration	NASAL		

Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
PHENYLEPHRINE HYDRO CHLO RIDE (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII: 1WS297W6MV)	PHENYLEPHRINE HYDROCHLORIDE	1.25 mg in 1 mL	

Inactive Ingredients		
Ingredient Name	Strength	
BENZALKONIUM CHLORIDE (UNII: F5UM2KM3W7)		
EDETATE DISO DIUM ANHYDRO US (UNII: 8 NLQ36 F6 MM)		
GLYCERIN (UNII: PDC6A3C0OX)		
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)		
POTASSIUM PHO SPHATE, UNSPECIFIED FORM (UNII: B7862WZ632)		

WATER (UNII: 059QF0KO0R)	
SODIUM PHO SPHATE DIBASIC DIHYDRATE (UNII: 9425516 E2T)	

Product Characteristics			
Color	WHITE (Clear)	Score	
Shape		Size	
Flavor		Imprint Code	
Contains			

Packaging			
# Item Coo	e Package Description	Marketing Start Date	Marketing End Date
1 NDC:63029-4	1 in 1 CARTON	0 1/0 1/20 17	
1	15 mL in 1 BOTTLE, DROPPER; 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	0 1/0 1/20 17	

Labeler - Medtech Products Inc. (122715688)

Revised: 6/2020 Medtech Products Inc.