

**CVS CHILDREN DECONGESTANT NOSE DROPS - phenylephrine hydrochloride solution
TAI GUK PHARM. CO., LTD.**

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.

Drug Facts

Active ingredient	Purpose
Phenylephrine Hydrochloride USP 0.125%.....	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

- do not exceed recommended dosage
- do not use with any other products containing decongestants

Ask a doctor before use if the child has

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

When using this product temporary discomfort may occur such as:

- burning
- stinging
- sneezing
- increase in nasal discharge
- the use of this dispenser by more than one person may spread infection

Stop use and ask a doctor if

- nervousness, dizziness, or sleeplessness occurs
- 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.

Keep out of reach of children. In case of overdose, get medical help or contact a Poison Control Center right away.

Directions (Nasal use only)

- children 2 to under 6 years (with adult supervision): 2 to 3 drops into each nostril, not more often than every 4 hours
- children under 2 years of age: Consult a physician

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, Edetate Disodium, Glycerin, Polyethylene Glycol, Potassium Phosphate Monobasic, Purified Water, Sodium Phosphate Dibasic



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CVS CHILDREN DECONGESTANT NOSE DROPS			
phenylephrine hydrochloride solution			
Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:68 169-9930
Route of Administration	NASAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
PHENYLEPHRINE HYDROCHLORIDE (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII:1WS297W6MV)	PHENYLEPHRINE HYDROCHLORIDE	1.25 mg in 1 mL

Inactive Ingredients

Ingredient Name	Strength
BENZALKONIUM CHLORIDE (UNII: F5UM2KM3W7)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	
GLYCERIN (UNII: PDC6A3C0OX)	
POLYETHYLENE GLYCOL (UNII: 3WJQ0SDW1A)	
WATER (UNII: 059QF0K00R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:68169-9930-6	1 in 1 CARTON		
1		15 mL in 1 BOTTLE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part341	07/12/2010	

Labeler - TAIGUK PHARM. CO., LTD. (631101656)

Revised: 7/2010

TAI GUK PHARM. CO., LTD.