CHILDRENS UNIPHED NASAL DECONGESTANT- pseudoephedrine hydrochloride liquid Rij Pharmaceutical Corporation

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

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Active ingredient (in each 5 mL*1)

Pseudoephedrine HCl, USP 15 mg

1 * 5 mL = one teaspoonful

Purpose

Nasal Decongestant

Uses

- temporarily relieves nasal congestion due to the common cold, hay fever or other upper respiratory allergies and nasal congestion associated with sinusitis
- temporarily relieves sinus congestion and pressure
- promotes nasal and/or sinus drainage

Warnings

Do not use if you are now taking a prescription monoamine oxidase inhibitor (MAOI) (certain drugs for depression, psychiatric or emotional conditions, or Parkinson's disease), or for 2 weeks after stopping the MAOI drug. If you do not know if your prescription drug contains an MAOI, ask a doctor or pharmacist before giving this product.

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

Stop use and ask a doctor if

- you get nervous, dizzy, or sleepness
- symptoms do not improve within 7 days or are accompanied by fever

If pregnant or breast-feeding,

ask a health professional before use

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

Directions

- take every 4 to 6 hours
- do not take more than 4 doses in 24 hours

children under 2 years of age	ask a doctor	
children 2 to under 6 years of	one (1) teaspoonful	
20 E	` ' 1	
children 6 to under 12 years of	two (2) to separatule	
adults and children 12 years of	of four (4) teaspoonfuls	
age and over		

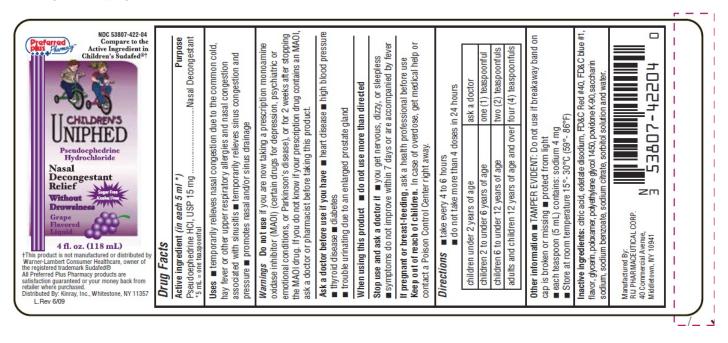
Other information

- TAMPER EVIDENT: Do not use if breakaway band on cap is broken or missing
- protect from light
- each teaspoon (5 mL) contains: sodium 4 mg
- Store at room temperature 15° 30°C (59° 86°F)

Inactive ingredients

citric acid, edetate disodium, FD&C Red #40, FD&C blue #1, flavor, glycerin, poloxamer, polyethylene glycol, povidone K-90, saccharin sodium, sodium benzoate, sodium citrate, sorbitol solution, and water

PRINCIPAL DISPLAY PANEL



CHILDRENS UNIPHED NASAL DECONGESTANT pseudoephedrine hydrochloride liquid Product Information Product Type HUMAN OTC DRUG Item Code (Source) NDC:53807-422

Active Ingredient/Active Moiety				
Ingredient Name	Basis of Strength	Strength		
Pseudoephedrine hydrochloride (UNII: 6 V9 V2RYJ8N) (Pseudoephedrine -	Pseudo ephedrine	15 mg		

Inactive Ingredients			
Ingredient Name	Strength		
anhydrous citric acid (UNII: XF417D3PSL)			
edetate disodium (UNII: 7FLD91C86K)			
FD&C blue no. 1 (UNII: H3R47K3TBD)			
FD&C red no. 40 (UNII: WZB9127XOA)			
glycerin (UNII: PDC6A3C0OX)			
poloxamer 407 (UNII: TUF2IVW3M2)			
polyethylene glycols (UNII: 3WJQ0SDW1A)			
povidone K90 (UNII: RDH86HJV5Z)			
water (UNII: 059QF0KO0R)			
saccharin sodium (UNII: SB8ZUX40TY)			
sodium benzoate (UNII: OJ245FE5EU)			
sodium citrate (UNII: 1Q73Q2JULR)			
sorbitol (UNII: 506T60A25R)			

Product Characteristics			
Color	PURPLE	Score	
Shape		Size	
Flavor	GRAPE	Imprint Code	
Contains			

l	Packaging				
# Item Code Package Description		Marketing Start Date	Marketing End Date		
ı	1 NDC:53807-422-04	118 mL in 1 BOTTLE; Type 0: Not a Combination Product	03/16/1999		

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH FINAL	part341	03/16/1999	

Labeler - Rij Pharmaceutical Corporation (144679156)

Establishment				
Name	Address	ID/FEI	Business Operations	
Rij Pharmaceutical Corporation		144679156	manufacture(53807-422)	

Revised: 4/2018

Rij Pharmaceutical Corporation