

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 sleepiness
- 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 age	one (1) teaspoonful
children 6 to under 12 years of age	two (2) teaspoonfuls
adults and children 12 years of age and over	four (4) teaspoonfuls


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

Drug Facts	Purpose Pseudoephedrine HCl, USP 15 mg Nasal Decongestant *5 mL = one teaspoonful	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 taking 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 sleepless ■ 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								
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								Manufactured By: RUI PHARMACEUTICAL CORP. 40 Commercial Avenue, Middletown, NY 10941								

CHILDRENS UNIPHED NASAL DECONGESTANT

pseudoephedrine hydrochloride liquid

Product Information

Product Type

HUMAN OTC DRUG

Item Code (Source)

NDC:53807-422

Route of Administration ORAL

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
Pseudoephedrine hydrochloride (UNII: 6 V9 V2RYJ8N) (Pseudoephedrine - UNII:7CUC9DDI9F)	Pseudoephedrine hydrochloride	15 mg in 5 mL

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: 059QF0K00R)	
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			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
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)

