RINOSAN PROPO NASAL DECONGESTANT- ephedrine hydrochloride spray
Bee Right LLC

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.

Rinosan PROPO Nasal Decongestant Spray

Drug Facts

Active Ingredient

Ephedrine Hydrochloride 0.5%

Purpose

Nasal Decongestant

Uses

- temporarily relieves nasal congestion due to the common cold, hay fever (allergic rhinitis)
- temporarily relieves stuffy nose
- temporarily restores freer breathing through the nose
- reduces swelling of nasal passages; shrinks swollen membranes
- helps decongest sinus openings and passages;
- promotes nasal and/or sinus drainage; temporarily relieves sinus congestion and pressure

Warnings

Consult a doctor before use if you have:

• heart disease • high blood pressure • thyroid disease • diabetes • difficulty in urination due to enlargement of the prostate gland

When using this product

- use of this container by more than one person may spread infection
- this product may cause temporary discomfort such as burning, stinging, sneezing, or an increase in nasal discharge
- do not use this product for more than 3 days; use only as directed. Frequent or prolonged use may cause nasal congestion to recur or worsen

Do not

- exceed recommended dosage

Stop use and consult a doctor if:

symptoms persist

If pregnant or breastfeeding,

consult a health care professional before use.

Keep out of reach of children.

If swallowed, get medical help or contact a Poison Control Center right away.

Directions

Adults and children 12 year of age and over	2 or 3 sprays in each nostril not more than once every 4 hours
Children 6 to under 12 years of age (with adult supervision)	1 or 2 sprays in each nostril not more than once every 4 hours
Children under 6 years of age	Consult a doctor

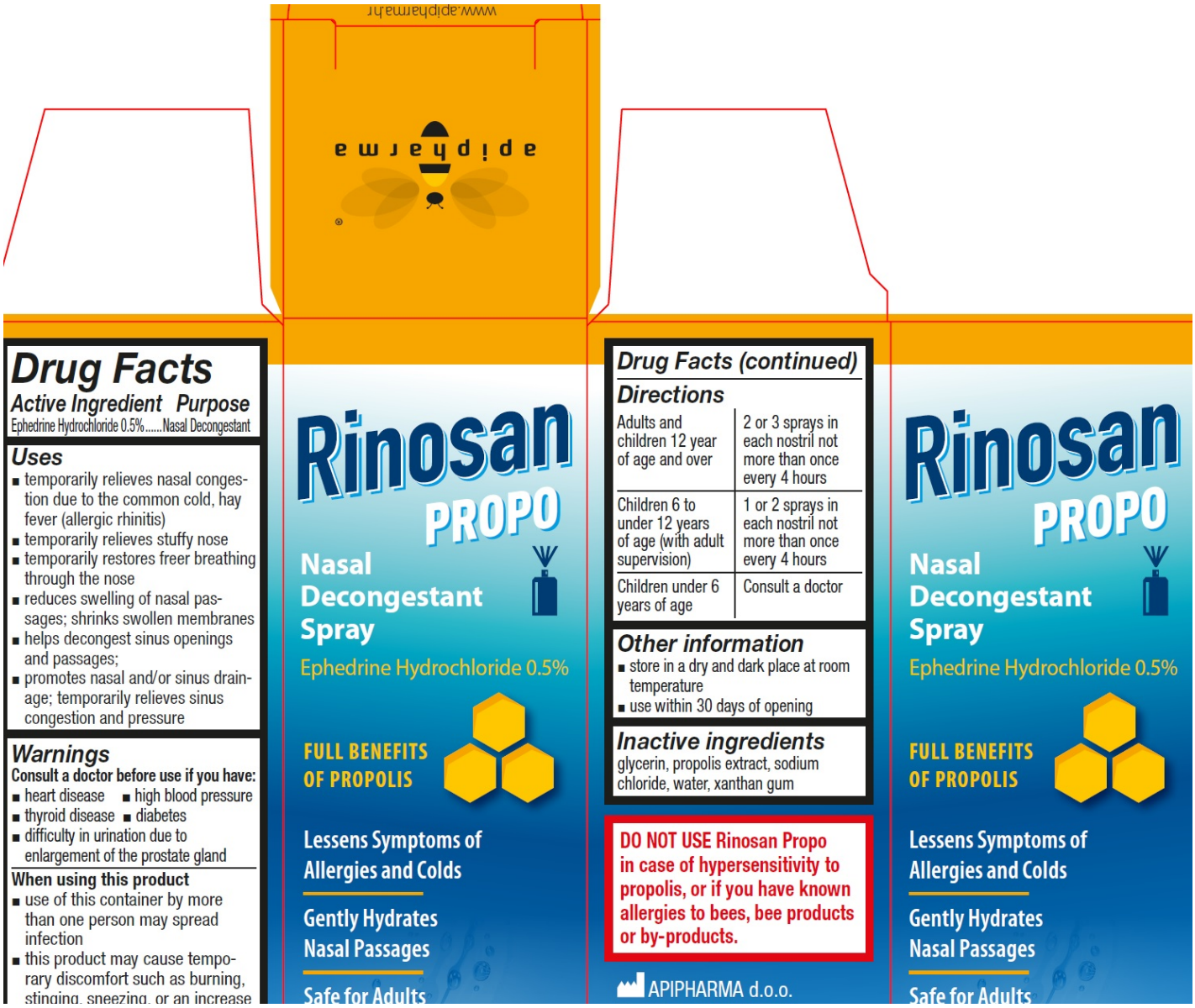
Other information

- store in a dry and dark place at room temperature
- use within 30 days of opening

Inactive ingredients

glycerin, propolis extract, sodium chloride, water, xanthan gum

Package Labeling:



in nasal discharge
- do not use this product for more than 3 days; use only as directed. Frequent or prolonged use may cause nasal congestion to recur or worsen
- **do not exceed recommended dosage**

Stop use and consult a doctor if symptoms persist

If pregnant or breastfeeding, consult a health care professional before use.

Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.

In case of hypersensitivity to propolis the use of **Rinosan propo** spray is not recommended

and Children

EUROPEAN PRODUCT

1 fl oz (30 mL)

Jeronima Kavanjina 26
10090 Zagreb, Croatia, EU

Made in Croatia, EU

Distributed by Bee Right LLC
807 Forrest St NW
Atlanta GA 30318

Batch number and expiration date are printed on the bottom of the packaging.

Consult instructions for use

NDC 72086

21 PAP

HR 2816 EU

CE

apipharma

US-10
2018-02

and Children

EUROPEAN PRODUCT

1 fl oz (30 mL)

3 858882 103633

LOT

www.apipharma.hr

RINOSAN PROPO NASAL DECONGESTANT

ephedrine hydrochloride spray

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:71952-040
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
EPHEDRINE HYDROCHLORIDE (UNII: NLJ6390P1Z) (EPHEDRINE - UNII:GN83C131XS)	EPHEDRINE HYDROCHLORIDE	5 mg in 1 mL

Inactive Ingredients	
Ingredient Name	**Strength**
GLYCERIN (UNII: PDC6A3C0OX)	
SODIUM CHLORIDE (UNII: 451W47IQ8X)	

WATER (UNII: 059QF0KO0R)	
XANTHAN GUM (UNII: TTV12P4NEE)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:71952-040-00	1 in 1 BOX	07/01/2018	
1		30 mL in 1 BOTTLE, SPRAY; 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	07/01/2018	

Labeler - Bee Right LLC (080988303)

Revised: 7/2018 Bee Right LLC