

**RINOSAN PROPO NASAL DECONGESTANT- ephedrine hydrochloride spray**  
**Apipharmausa, 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 ingredients***

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:**

**Drug Facts (continued)**

**Directions**  
Adults and children 12 years 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

**DO NOT USE Rinosan PROPO in case of hypersensitivity to propolis, or if you have known allergies to bees, bee products or by-products.**

APIPHARMA d.o.o.  
Jerolimna Kavanjina 26  
10090 Zagreb, Croatia, EU  
Made in Croatia, EU  
Distributed by: Apipharma, LLC  
2311 West Alameda Drive  
Tempe, AZ 85282  
Phone: (602) 385-8181  
Batch number and expiration date are printed on the bottom of the packaging.  
Consult instructions for use NDC 71993-040-00

**Rinosan PROPO**  
Nasal Decongestant Spray  
Ephedrine Hydrochloride 0.5%

**Rinosan PROPO**  
Nasal Decongestant Spray  
Ephedrine Hydrochloride 0.5%

**Drug Facts**  
**Active ingredient Purpose**  
Ephedrine Hydrochloride 0.5% - Nasal Decongestant

**Uses**  
• temporarily relieves nasal congestion due to the common cold, hay fever (allergic rhinitis)  
• temporarily relieves stuffy nose  
• temporarily restores free 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.

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

2

**Drug Facts (continued)**

**Directions**  
Adults and children 12 years 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

**DO NOT USE Rinosan PROPO in case of hypersensitivity to propolis, or if you have known allergies to bees, bee products or by-products.**

APIPHARMA d.o.o.  
Jerolimna Kavanjina 26  
10090 Zagreb, Croatia, EU  
Made in Croatia, EU  
Distributed by: Apipharma, LLC  
2311 West Alameda Drive  
Tempe, AZ 85282  
Phone: (602) 385-8181  
Batch number and expiration date are printed on the bottom of the packaging.  
Consult instructions for use NDC 71993-040-00

**Rinosan PROPO**  
Nasal Decongestant Spray  
Ephedrine Hydrochloride 0.5%

**Rinosan PROPO**  
Nasal Decongestant Spray  
Ephedrine Hydrochloride 0.5%

**Drug Facts**  
**Active ingredient Purpose**  
Ephedrine Hydrochloride 0.5% - Nasal Decongestant

**Uses**  
• temporarily relieves nasal congestion due to the common cold, hay fever (allergic rhinitis)  
• temporarily relieves stuffy nose  
• temporarily restores free 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.

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

4

**Drug Facts (continued)**

**Directions**  
Adults and children 12 years 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**  
Benzalkonium chloride, calcium chloride, disodium phosphate, eucalyptus globulus oil, menthol, potassium chloride, sodium chloride, water

**MENTHOL FRESHNESS**

**Lessens Symptoms of Allergies and Colds**  
Gently Hydrates Nasal Passages  
Safe for Children and Adults

APIPHARMA d.o.o.  
Jerolimna Kavanjina 26  
10090 Zagreb, Croatia, EU  
Made in Croatia, EU  
Distributed by: Apipharma, LLC  
2311 West Alameda Drive  
Tempe, AZ 85282  
Phone: (602) 385-8181  
Batch number and expiration date are printed on the bottom of the packaging.  
Consult instructions for use NDC 71993-030-00

**Rinosan MINT**  
Nasal Decongestant Spray  
Ephedrine Hydrochloride 0.5%

**Rinosan MINT**  
Nasal Decongestant Spray  
Ephedrine Hydrochloride 0.5%

**Drug Facts**  
**Active ingredient Purpose**  
Ephedrine Hydrochloride 0.5% - Nasal Decongestant

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

**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.

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

1

**Drug Facts (continued)**

**Directions**  
Adults and children 12 years 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**  
Benzalkonium chloride, calcium chloride, disodium phosphate, eucalyptus globulus oil, menthol, potassium chloride, sodium chloride, water

**MENTHOL FRESHNESS**

**Lessens Symptoms of Allergies and Colds**  
Gently Hydrates Nasal Passages  
Safe for Children and Adults

APIPHARMA d.o.o.  
Jerolimna Kavanjina 26  
10090 Zagreb, Croatia, EU  
Made in Croatia, EU  
Distributed by: Apipharma, LLC  
2311 West Alameda Drive  
Tempe, AZ 85282  
Phone: (602) 385-8181  
Batch number and expiration date are printed on the bottom of the packaging.  
Consult instructions for use NDC 71993-030-00

**Rinosan MINT**  
Nasal Decongestant Spray  
Ephedrine Hydrochloride 0.5%

**Rinosan MINT**  
Nasal Decongestant Spray  
Ephedrine Hydrochloride 0.5%

**Drug Facts**  
**Active ingredient Purpose**  
Ephedrine Hydrochloride 0.5% - Nasal Decongestant

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

**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.

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

3

# Rinosan PROPO

Nasal Decongestant Spray  
Ephedrine Hydrochloride 0.5%  
1 fl oz (30 mL)

APIPHARMA d.o.o.,  
Jeronima Kavanjina 26, 10090 Zagreb,  
Hrvatska, EU. Made in Croatia, EU.

REF 3009

US-10  
APIPHARMAUSA

THIS UNIT NOT LABELED FOR RETAIL  
SALE. PLEASE SEE OUTER CONTAINER FOR  
COMPLETE DRUG FACT INFORMATION.

DO NOT USE Rinosan Propo in case of  
hypersensitivity to propolis, or if you have known  
allergies to bees, bee products or by-products.

Distributed by Apipharmausa, LLC  
2331 West Alameda Drive, Tempe, AZ 85282  
Phone: (602) 385-8181

Consult Instructions for use



## RINOSAN PROPO NASAL DECONGESTANT

ephedrine hydrochloride spray

### Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:73061-002
Route of Administration	NASAL		

### 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)	
PROPOLIS WAX (UNII: 6Y8XYV2NOF)	
SODIUM CHLORIDE (UNII: 451W47IQ8X)	
WATER (UNII: 059QF0KO0R)	
XANTHAN GUM (UNII: TTV12P4NEE)	

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:73061-002-30	1 in 1 BOX	03/10/2020	
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	03/10/2020	

**Labeler** - Aipharmausa, LLC (117030000)

Revised: 3/2020

Aipharmausa, LLC