

RINOSAN MINT 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 MINT 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
- 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.

Directions

Adults and children 12 year of age and over

Children 6 to under 12 years of age (with adult supervision)

Children under 6 years of age

2 or 3 sprays in each nostril not more than once every 4 hours

1 or 2 sprays in each nostril not more than once every 4 hours

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

Package Labeling:

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Active Ingredient Purpose
Ephedrine Hydrochloride 0.5%.....Nasal Decongestant

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Drug Facts (continued)
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Rinosan MINT
Nasal Decongestant Spray
Ephedrine Hydrochloride 0.5%

PLEASANT MENTHOL FRESHNESS

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

APIPHARMA d.o.o.

<p>in nasal discharge</p> <ul style="list-style-type: none"> 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 <p>Stop use and consult a doctor if symptoms persist</p> <p>If pregnant or breastfeeding, consult a health care professional before use.</p> <p>Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.</p>	<p>and Adults</p>  <p>EUROPEAN PRODUCT</p>	<p>Jeronima Kavanjina 26 10090 Zagreb, Croatia, EU</p> <p>Made in Croatia, EU</p> <p>Distributed by Bee Right LLC 807 Forrest St NW Atlanta GA 30318</p> <p>Batch number and expiration date are printed on the bottom of the packaging.</p> <p>Consult instructions for use</p> <p>NDC 72086</p> 	<p>and Adults</p>  <p>EUROPEAN PRODUCT</p>
<p>1 fl oz (30 mL)</p>		<p>US-10 2018-05</p> 	<p>1 fl oz (30 mL)</p>
		 <p>3 858882 103626</p> <p>LOT</p>  <p>www.apipharma.hr</p>	

<h1>Rinosan</h1> <h2>MINT</h2>  <p>Nasal Decongestant Spray</p> <p>Ephedrine Hydrochloride 0.5%</p> <p>1 fl oz (30 mL)</p>	<p>APIPHARMA d.o.o. Jeronima Kavanjina 26 10090 Zagreb, Hrvatska, EU Made in Croatia, EU.</p> <p>REF 3008 US-10</p> <p>CE</p> <p>THIS UNIT NOT LABELED FOR RETAIL SALE. PLEASE SEE OUTER CONTAINER FOR COMPLETE DRUG FACT INFORMATION.</p> <p>Distributed by Bee Right LLC, 807 Forrest St NW, Atlanta GA 30318</p> <p>Consult Instructions for use</p> <p>LOT</p> 
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RINOSAN MINT NASAL DECONGESTANT

ephedrine hydrochloride spray

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:71952-030
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
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EPHEDRINE HYDROCHLORIDE (UNII: NLJ6390P1Z) (EPHEDRINE - UNII:GN83C131XS)	EPHEDRINE HYDROCHLORIDE	5 mg in 1 mL
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Inactive Ingredients

Ingredient Name	Strength
BENZALKONIUM CHLORIDE (UNII: F5UM2KM3W7)	
CALCIUM CHLORIDE (UNII: M4I0D6VV5M)	
SODIUM PHOSPHATE, DIBASIC, ANHYDROUS (UNII: 22ADO53M6F)	
EUCALYPTUS OIL (UNII: 2R04ONI662)	
MENTHOL (UNII: L7T10EIP3A)	
POTASSIUM CHLORIDE (UNII: 660YQ98110)	
SODIUM CHLORIDE (UNII: 451W47IQ8X)	
WATER (UNII: 059QF0KO0R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:71952-030-00	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