

## INSTRUCTIONS FOR USE:

# RUPANASE<sup>®</sup>

## Allergy Nasal Spray

**Instructions for Use** – please read attentively  
Read this information carefully before you start using **Rupanase Allergy Nasal Spray**.

**DO NOT THROW THIS LEAFLET AWAY!** It contains important information.

If you have any questions about **Rupanase Allergy Nasal Spray** please ask your healthcare provider, pharmacist, or distributor.

### 1. What is Rupanase Allergy Nasal Spray and what is it used for

**Rupanase Allergy Nasal Spray** is a nasal spray for treatment and prevention of allergic rhinitis symptoms.

**Rupanase Allergy Nasal Spray** is a medical device which contains Ectoin<sup>®</sup>, a natural cell-protective molecule with inflammation-reducing and membrane-stabilizing properties.

**Rupanase Allergy Nasal Spray** is a slightly hypertonic solution and reduces the harmful influences of allergens and airborne particles. It supports the regeneration process of irritated nasal mucosa caused by allergens.

**Rupanase Allergy Nasal Spray** reduces allergen induced inflammations of the nasal mucosa. Alleviates allergic symptoms like runny nose, itching nose, and nasal congestion.

**Rupanase Allergy Nasal Spray** is free of preservatives. Rupanase Allergy Nasal Spray is suitable for sensitive noses and has no habituation effect.

### 2. Warnings and precautions

- **Rupanase Allergy Nasal Spray** should not be used in the case of hypersensitivity to Ectoin<sup>®</sup> or any of the other ingredients of the nasal spray.
- If allergic reactions occur, the use of **Rupanase Allergy Nasal Spray** must be discontinued immediately.
- Do not use if the device is damaged or punctured.

- To ensure safe hygiene, each nasal spray bottle should only be used by one person.
- Do not use for more than 3 months after opening.
- **Rupanase Allergy Nasal Spray** should be kept out of reach of children.

### 3. What you need to know before using Rupanase Allergy Nasal Spray

There are no data available regarding interactions between **Rupanase Allergy Nasal Spray** and other topical nasal treatments.

### 4. How to use Rupanase Allergy Nasal Spray

Always use **Rupanase Allergy Nasal Spray** according to these instructions for use. Spray 1-2 sprays in each nostril several times a day, unless otherwise prescribed by a healthcare provider.

Use in children < 2 years must be under the supervision of a healthcare provider. Children < 2 years should not administer more than 10 applications (of 2 sprays per nostril) per day. There is no dosage restriction for persons ≥ 2 years. Do not use **Rupanase Allergy Nasal Spray** for more than 30 days continuously.

Before using **Rupanase Allergy Nasal Spray** for the first time, take off the cap and pump the bottle 2-3 times in upright position to release the air from the pump. Do not cut the tip.

1. Gently blow your nose to clean your nostrils.
2. Remove the cap from the bottle.
3. Hold the bottle with your index and middle finger on either side of the finger rests and your thumb underneath the bottle. Bend your head slightly forward and close one nostril by gently pressing against the side of your nose with your finger.
4. Insert the tip of the spray into your nostril. While pressing down the pump quickly and firmly, breath- in gently through the nose.
5. Insert the tip into your other nostril.
6. Repeat steps described above for the other nostril.
7. Wipe the exposed tip of the bottle with a clean lint- free cloth.
8. Replace cap on the bottle.

### Explanation of the symbols used on the product



CE mark with  
Notified Body  
number



Legal  
manufacturer



Temperature  
limitation



Product is sterile  
by aseptic  
filtration



Lot  
number



Use by date  
(expiry date)



Please consider the  
instructions for use



Please do not use  
damaged or punctured  
packaging



### 5. Possible side effects of Rupanase Allergy Nasal Spray

**Rupanase Allergy Nasal Spray** is well tolerated. Up to now, no regularly occurring or persisting side effects are known.

Please inform your healthcare provider, pharmacist, or distributor of the device if you notice side effects that are associated with the use of **Rupanase Allergy Nasal Spray**.

If conditions persist or worsen, contact your healthcare provider or pharmacist.

### 6. How to store Rupanase Allergy Nasal Spray

The expiry date of **Rupanase Allergy Nasal Spray** is printed on the box and on the bottle.

**Rupanase Allergy Nasal Spray** must not be used after the expiry date has passed.

**Rupanase Allergy Nasal Spray** should be stored between 2 °C – 25 °C.

Store **Rupanase Allergy Nasal Spray** out of the reach of children.

### 7. Additional information

If **Rupanase Allergy Nasal Spray** is applied within its intended use, there is no evidence for a particular risk during pregnancy or breast-feeding. Contact your healthcare provider prior to use.

**Rupanase Allergy Nasal Spray** is suitable for children.

Children 10 years of age and younger and patients unable to use **Rupanase Allergy Nasal Spray** on their own should be assisted during the application of **Rupanase Allergy Nasal Spray**.

### 8. Content of Rupanase Allergy Nasal Spray

20 mL solution

One spray contains 0.14 mL solution

### Ingredients

Ectoin®, Sea Salt, and water

### 9. Legal Manufacturer

bitop AG Stockumer Str. 28,  
58453 Witten, Germany



### 10. Date of information:

August 2020

### Marketed by:

iNova Pharmaceuticals (Pty) Ltd  
Co. Reg. No. 1952/001640/07  
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Tel: +27 11 0870000  
www.inovapharma.co.za

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CE mark with  
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manufacturer



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limitation



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