

# Rhinase Aqueous Nasal Spray

## 1. What this product is and what it is used for

Rhinase Aqueous Nasal Spray (called 'Rhinase' in this leaflet) contains a medicine called fluticasone propionate. This belongs to a group of medicines called steroids (also called 'cortico-steroids').

- Steroids work by reducing inflammation.
- They reduce swelling and irritation in your nose.
- This helps to relieve itching, sneezing and your blocked or runny nose.

Rhinase is used to prevent and treat:

- Inflammation in the lining of your nose (rhinitis) due to seasonal allergies, such as Hay fever.
- Inflammation in the lining of your nose (rhinitis) due to year-round (perennial) allergies, such as animal allergies.

## 2. What you need to know before you use this product

Do not take Rhinase if

- You are allergic to fluticasone propionate or any of the other ingredients of this medicine (listed in section 6).

### **Warnings and precautions**

Talk to your doctor or pharmacist before using Rhinase:

- If you have ever had an operation on your nose.
- If you have an infection in your nose.

Contact your doctor if you experience blurred vision or other visual disturbances.

### **Other medicines and Rhinase**

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines, including medicines obtained without a prescription. Tell your doctor if you are taking the following medicines, before starting to use Rhinase if:

- you have had steroids for a long time, either as an injection or by your mouth.
- you are taking a type of antiviral medicine known as a protease inhibitor (e.g. ritonavir) or cobicistat containing products which may increase the effects of fluticasone propionate. Your doctor may wish to monitor you carefully if you are taking these medicines.
- you are taking certain medicines used to treat fungal infections (e.g. ketoconazole).

### **Taking Rhinase with food and drink**

You can use Rhinase at any time of day, with or without food.

#### **Pregnancy and breastfeeding**

If you are pregnant or breastfeeding, think you may be pregnant or planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

#### **Driving and using machines**

Rhinase is not likely to affect you being able to drive or use any tools or machines.

Rhinase contains benzalkonium chloride

Benzalkonium chloride may cause problems with your breathing (bronchospasm). Benzalkonium chloride may also cause irritation or swelling inside the nose, especially if used for a long time.

### **3. How to use this product.**

Always use this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

Do not use in children under 4 years old.

- Only use in your nose, contact with eyes should be avoided.
- It takes a few days for this medicine to work. So, keep using it, even though you may not feel better straight away.
- Use the spray every day.

#### **Adults and children (aged 12 and over)**

- The usual starting dose is 2 sprays into each nostril once a day, preferably in the morning.
- The most you would use over 24 hours is normally 8 sprays (4 sprays per nostril).
- As you become better, your doctor may ask you to use a lower dose - one spray into each nostril once a day.
- If your symptoms then get worse, your dose may be increased back to the starting dose.

#### **Children aged 4 to 11 years**

- The usual starting dose is one spray into each nostril once a day, preferably in the morning.
- The most you would use over 24 hours is normally 4 sprays (2 sprays per nostril).

#### **Preparing your spray**

Each spray has a dust cap which protects the nozzle and keeps it clean.

Remember to take this off before using the spray.

A new spray (or one that has not been used for a few days), may not work first time. You need to 'prime' the spray by pumping the spray a few times until a fine mist is produced.

1. Hold the bottle as shown and make sure it is pointed away from you.
2. Put your forefinger and middle finger on the collar either side of the nozzle and put your thumb underneath the bottle.
3. Keep your thumb still and press down with your fingers to pump the spray.

- If the spray does not work and you think it may be blocked, you will need to clean it. Please see the section below, Cleaning your spray.

- Never try to unblock or enlarge the tiny spray hole with a pin or other sharp object. This will damage the way the spray works.

#### **Using your spray**

1. Shake the bottle and take off the dust cap.
2. Blow your nose gently.
3. Close one nostril with your finger as shown and put the nozzle in the other nostril. Tilt your head forward slightly and keep the bottle upright.  
Hold the bottle as shown.
4. Start to breathe in slowly through your nose. While you are breathing in press down firmly on the collar with your fingers. A spray of fine mist will go into your nostril.
5. Breathe out through your mouth.
6. Repeat step 4 to use a second spray in the same nostril.
7. Remove the nozzle from this nostril and breathe out through your mouth.
8. Repeat steps 3 to 6 for your other nostril.
9. After using your spray, wipe the nozzle carefully with a clean tissue or handkerchief, and replace the dust cap.

### **Cleaning your spray**

Clean your spray at least once a week, or more often if it gets blocked.

1. Take the dust cap off by gently squeezing the ribbed sides between your finger and thumb and lifting it off. Do not twist it off.
2. Pull upwards on the white collar to remove the nozzle.
3. Soak the nozzle and dust cap in warm water for a few minutes.
4. Then rinse under a running tap.
5. Shake off the excess water and let them dry in a warm place.
6. Put the nozzle back on the spray.
7. 'Prime' the bottle as described in the section above, Preparing your spray.

### **If you use more Rhinase than you should**

Tell your doctor if you use more than you were told to.

It is important that you take your dose as stated on the pharmacist's label or as advised by your doctor. You should use only as much as your doctor recommends; using more or less may make your symptoms worse.

### **If you forget to use Rhinase**

If you miss a dose, just use the next dose when it is due. Do not take a double dose to make up for the forgotten dose.

### **If you stop using Rhinase**

Do not stop treatment even if you feel better, unless your doctor tells you to stop. If you do stop, the symptoms may come back.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

## **4. Possible side effects**

Like all medicines, this medicine can cause side effects, although not everybody gets them. The following side effects may happen with this medicine:

Allergic reactions: get a doctor's help straight away

A small number of people get allergic reactions to Rhinase, which can develop into a more serious, even life-threatening problem if not treated. Symptoms include;

- becoming very wheezy, coughing or having difficulty with breathing.
- suddenly feeling weak or light-headed (which may lead to collapse or loss of consciousness).
- swelling around the face, mouth or tongue.
- skin rashes or redness.

If this happens, tell your doctor straight away – you may need urgent medical treatment.

Allergic reactions to Rhinase are very rare (These affect less than 1 in 10,000 people).

Immediately after you use your spray

- You may sneeze a little, but this soon stops.
- Very occasionally you may find you get an unpleasant taste or smell.

Tell your doctor as soon as possible if you notice any of the following side effects:

Other side effects include:

Very common (may affect more than 1 in 10 people)

- Nose bleeds.

Common (may affect up to 1 in 10 people)

- Headache.
- Unpleasant taste.
- Unpleasant smell.
- A dry or painful nose or throat.

Very rare (may affect up to 1 in 10,000 people)

- Skin reaction – which can range from red, itchy rash and blotches to a more severe skin reaction such as dry, cracked and peeling skin.
- Problems with your eyes such as pain or blurred vision.
- Damage to your nose

Not known: frequency cannot be estimated from the available data

- Blurred vision.
- Sores in the nose.

Very rarely, the normal production of steroids in your body may be affected. This is more likely to happen if you use high doses for a long time. Your doctor will help stop this happening by making sure you use the lowest dose of steroid which controls your symptoms. In children this side effect can rarely cause them to grow more slowly than others. Children who receive this treatment for a long period of time will have their height checked regularly by their doctor.

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist, or nurse. This includes any possible side effects not listed in this leaflet.

## **5. How to store this product**

- Keep this medicine out of the sight and reach of children.
- Store between 4°C and 30°C.
- Do not use this medicine after the expiry date which is stated on the label and carton. The expiry date refers to the last day of that month.
- Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines if you no longer use. These measures will help to protect the environment.

## **6. Further information**

### **a. What this product contains**

The active substance is: Fluticasone propionate.

The other ingredients are: Dispersible cellulose, Glycerin, Polysorbate 80, water purified and the preservatives Benzalkonium chloride and Phenylethyl alcohol.

### **b. What this product looks like and contents of the pack**

Rhinase is available in a metered dose. Each amber colored glass bottle delivers 120 metered sprays. Each spray contains 50 micrograms of fluticasone propionate.

### **c. Marketing Authorization Holder and Manufacturer**

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### **d. This leaflet was last revised in**

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