

Ryaltris

Nasal Spray

Active substance

olopatadine (as hydrochloride) 600 mcg
mometasone furoate (as monohydrate) 25 mcg

- For information regarding inactive ingredients: see section 2 – “Important information about some of the ingredients of the medicine” and section 6 – “Additional information”.
- **Read the entire leaflet carefully before using the medicine.** This leaflet contains concise information about the medicine. If you have additional questions, refer to the doctor or the pharmacist.
 - This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

1. What is the medicine intended for?

Ryaltris is used to **treat the symptoms of moderate to severe seasonal allergic rhinitis** (also called hay fever) **and perennial rhinitis** in adults and adolescents 12

Therapeutic class: To treat nasal congestion or to prevent and treat allergic rhinitis

Ryaltris contains two active substances: mometasone furoate and olopatadine.

- Mometasone furoate belongs to a group of medicines called corticosteroids (steroids) which reduce inflammation, often found in allergic rhinitis.
- Olopatadine belongs to a group of medicines called antihistamines. Antihistamines work by preventing the effects of substances such as histamine that the body produces as part of an allergic reaction - thus reducing symptoms of allergic rhinitis.
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2. Before using the medicine

Do not use this medicine if:

- if you are allergic to mometasone furoate, olopatadine or any of the other ingredients of this medicine (listed in section 6).
- if you have an **untreated infection in your nose**. Use of Ryaltris during an untreated infection in your nose, such as herpes, can worsen the infection. You should wait until the infection is resolved before you start using the nasal spray.
- if you have recently had an **operation on your nose** or you have **injured your nose**. You should not use the nasal spray until your nose has healed.

Special warnings regarding the use of the medicine

Talk to your doctor or pharmacist before taking Ryaltris

- if you have or have ever had **tuberculosis**.
- if you have any **other infection**.
- if you are taking other **steroid medicines**, either by mouth or by injection.

Talk to your doctor or pharmacist while you are using Ryaltris

- if you have difficulty in fighting infections (as your immune system is not functioning well) and you come into contact with anyone with **measles or chickenpox**. You should avoid coming into contact with anyone who has these infections.
- if you have an **infection of the nose or throat**.
- if you are using this medicine for **several months or longer**.
- if you have persistent **irritation to the nose or throat**
- if you experience **blurred vision** or other visual disturbances.

When steroid nasal sprays are used at high doses for long periods of time, side effects may occur due to the drug being absorbed in the body. Such side effects may include weight loss, fatigue, muscle weakness, low blood sugar, salt cravings, joint pains, depression and darkening of the skin. If this happens your doctor may recommend another medicine during periods of stress or elective surgery.

If you are not sure whether the above applies to you, talk to your doctor or pharmacist before using Ryaltris.

Children and adolescents

Ryaltris is not recommended in children below 12 years.

Taking Ryaltris for a long time can cause children and adolescents to grow more slowly. The doctor will **check your child's height regularly** and make sure he or she is taking the lowest possible effective dose.

Drug interactions

If you are taking or have recently taken other medicines, including non-prescription medicines and nutritional supplements, tell the doctor or the pharmacist. Especially if you are taking:

If you are taking other steroid medicines for allergy, either by mouth or injection, your doctor may advise you to stop taking them once you begin using Ryaltris.

If you are taking other medicines by oral or local route (nasal or eye drops) containing olopatadine or other antihistamines, your doctor may advise you to stop taking them once you begin using Ryaltris.

Some medicines may increase the effects of Ryaltris and your doctor may wish to monitor you carefully if you are taking these medicines (including some medicines for HIV: ritonavir, cobicistat).

Pregnancy and breast-feeding

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

Ryaltris should not be used during pregnancy unless considered appropriate by your doctor.

If you are taking Ryaltris, your doctor will discuss with you whether you should breast-feed considering the benefit to you of your therapy and the benefit to your baby of breast-feeding. You should not do both.

Driving and using machines

Very rarely, you may experience dizziness lethargy, fatigue and sleepiness. If this happens, do not drive or operate machinery. Please be aware that drinking alcohol may enhance these effects.

Important information about some of the ingredients of the medicine

Ryaltris contains benzalkonium chloride. This medicine contains 0.02 mg benzalkonium chloride in each actuation. Benzalkonium chloride may cause irritation or swelling inside the nose, especially if used for a long time.

3. How should you use the medicine?

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

Contact with the eyes should be avoided.

Adults and adolescents (12 years and above) The recommended dose is **two sprays into each nostril** in the morning and evening.

Use in children under 12 years

This medicine is not recommended for children under 12 years.

Method of administration

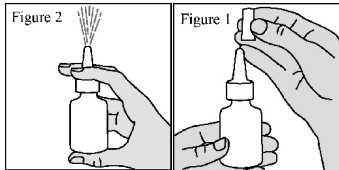
The spray is for nasal use.

Read the following instructions carefully and use only as directed.

Preparing the nasal spray bottle

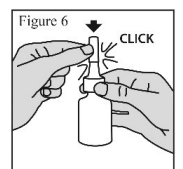
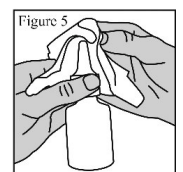
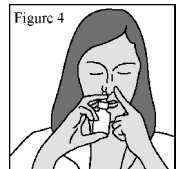
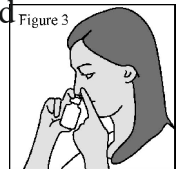
1. Shake the bottle for minimum 10 seconds and then remove the protective cap (see figure 1).
2. If you are using the spray for the first time you need to 'prime' the bottle by pumping into the air.

3. Put your forefinger and middle finger either side of the nozzle and your thumb underneath the bottle.
4. Point the nozzle away from you and then press down and release the pump 6 times until a fine mist appears (see figure 2).
5. Now your pump is primed and ready to use.
6. If you have not used the spray for 14 days or more, you need to “re-prime” the bottle by pumping the spray 2 times until a fine mist is produced



How to use your nasal spray

1. Shake the bottle for minimum 10 seconds before each use (morning and evening).
2. Gently blow your nose to clear your nostrils.
3. Close one nostril with your finger and carefully insert the spray tip into the other nostril, pointing it slightly toward the outside of the nose (see figure 3).
4. Tilt your head forward slightly, rapidly press down once and sniff gently at the same time.
5. Breathe out through your mouth (see figure 4).
6. Repeat the above steps and deliver a second spray in the same nostril.
7. Repeat with 2 sprays in the other nostril.
8. After using the spray, wipe the nozzle carefully with a clean handkerchief or tissue (see figure 5).
9. Replace the cap to avoid the nozzle becoming blocked, confirmed when you hear a “click”. (see figure 6).



Cleaning your nasal spray

If the nozzle gets blocked, do as described in the following steps:

- Remove the cap and gently pull off the nozzle.
- Wash the nozzle and cap in warm water and then rinse under a running tap.
- Do not try to unblock the nasal applicator by inserting a pin or other sharp object as this will damage the applicator and cause you not to get the right dose of medicine.
- Allow the cap and nozzle to dry in a warm place.
- Push the nozzle back onto the bottle and replace the cap, confirmed when you hear a “click”.
- The spray will need to be primed again with 2 sprays when first used after cleaning.

If you take more Ryaltris than you should You are unlikely to have any problems but if you are worried or if you have used doses higher than recommended over a long period, contact your doctor.

If you use steroids for a long time or in large amounts they may rarely affect some of your hormones. In children this may affect growth and development.

If you forget to take Ryaltris

Use your nasal spray as soon as you remember, then take the next dose at the usual time. Do not take a double dose to make up for a forgotten dose.

Follow the treatment as recommended by the doctor.

Do not stop treatment with the medicine without consulting the doctor.

If you stop taking Ryaltris

It is very important that you use your nasal spray regularly. Do not stop your treatment even if you feel better unless your doctor told you.

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

Do not take medicines in the dark! Check the label and the dose every time you take the medicine. Wear glasses if you need them.

If you have any other questions regarding use of the medicine, consult the doctor or the pharmacist.

4. Side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them. Do not be alarmed when reading the list of side effects. You may not experience any of them

Immediate hypersensitivity (allergic) reactions may occur after use of this product. These reactions may be severe. You should stop taking Ryaltris and get immediate medical help if you experience symptoms such as: swollen face, tongue or pharynx; trouble swallowing; hives; wheezing or trouble breathing.

Common side effects (effects that may affect up to one in 10 users):

- A bitter taste in your mouth;
- Nosebleed;
- Slight irritation of the inside of the nose;

Uncommon side effects (effects that may affect up to one in 100 users):

- Dizziness;
- Headaches;
- Sleepiness;
- Nasal dryness;
- Dry mouth;
- Abdominal pain;

- Nausea;
- Fatigue;

Rare side effects (effects that can affect up to one in 1,000 users):

- Bacterial vaginosis (bacterial infection of the vagina);
- Anxiety, depression, insomnia;
- Lethargy, migraine;
- Dry eye, blurred vision, eye discomfort;
- Ear pain;
- Sore throat;
- Sneezing;
- Throat irritation;
- Constipation;
- Sore tongue;
- Swelling and ulcers inside your nose.
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Side effects with unknown frequency (frequency cannot be estimated from the available data):

- Increase in pressure in the eye (glaucoma) and/ or cataracts causing visual disturbances;
- Damage to the partition in the nose which separates the nostrils;
- Difficulty in breathing and/or wheezing;
- Respiratory tract infection.

Systemic side effects (side effects concerning the whole body) may occur when this medicine is used at high doses for a long time. These effects are much less likely to occur if you use a steroid nasal spray than if you take steroids by mouth. These effects may vary in individual patients.

Nasal steroids can affect the normal production of hormones in your body, particularly if you use high doses for a long time. In children and adolescents this side effect can cause them to grow more slowly than others.

If a side effect occurs, if one of the side effects worsens, or if you suffer from a side effect not mentioned in this leaflet, consult your doctor.

Reporting side effects

Side effects may be reported to the Ministry of Health by clicking on the link “Report side effects due to medicinal treatment” found on the Ministry of Health website homepage (www.health.gov.il), which will direct you to the online form for reporting side effects, or by clicking on the following link:

<https://sideeffects.health.gov.il>.

5. How to store the medicine?

Avoid poisoning! This medicine and any other medicine must be kept in a closed place out of the reach and sight of children and/or infants to avoid poisoning. Do not induce vomiting without an explicit instruction from the doctor.

Do not use the medicine after the expiry date (exp. date) appearing on the package. The expiry date refers to the last day of that month.

Store below 25°C

Do not freeze.

The bottle should be used within 2 months of first opening.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Additional information

In addition to the active ingredient the medicine also contains:

microcrystalline cellulose and carmellose (E460), dibasic sodium phosphate heptahydrate (E 339), carmellose sodium (E 466), sodium chloride, benzalkonium chloride, disodium edetate, polysorbate 80 (E 433), hydrochloric acid (E 507), sodium hydroxide (E 524) and water for injections.

What Ryaltris looks like and contents of the pack

Ryaltris is a white, homogenous suspension.

Ryaltris is contained in a white, high density polyethylene bottle supplied with a metered- dose, manual polypropylene spray pump actuator. The actuator is protected by a HDPE purple cap.

Pack sizes:

1 bottle of 20 ml with 9 g suspension (56 actuations),

1 bottle of 20 ml with 18 g suspension (120 actuations),

1 bottle of 30 ml with 29 g suspension (240 actuations).

Not all pack sizes may be marketed.

Marketing Authorisation Holder:

**K.S.KIM INTERNATIONAL (S.K.- PHARMA) LTD., ISRAEL
94 YIGAL ALON STR., TEL-AVIV-YAFO, 6789139.**

Manufacturer:

Glenmark Pharmaceuticals s.r.o. Fibichova 143, 566 17 Vysoke Myto, Czech Republic

This leaflet was last revised in October 2023

Registration number of the medicine in the national drug registry of the Ministry of Health: