

Package leaflet: Information for the patient

Ryaltris® 25 micrograms/actuation + 600 micrograms/actuation nasal spray, suspension

mometasone furoate/olopatadine

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or 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.

What is in this leaflet:

1. What Ryaltris is and what it is used for
2. What you need to know before you take Ryaltris
3. How to take Ryaltris
4. Possible side effects
5. How to store Ryaltris
6. Contents of the pack and other information

1. What Ryaltris is and what it is used for

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.

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 years of age or older.

Seasonal allergic rhinitis (hay fever) is an allergic reaction which occurs at certain times of the year and is caused by breathing in pollen from trees, grasses, weeds and also moulds and fungal spores.

Perennial rhinitis occurs throughout the year and symptoms can be caused by a sensitivity to a variety of things including house dust mite, animal hair (or dander), feathers and certain foods.

Ryaltris **relieves the symptoms of allergies**, like runny nose, sneezing and itchy or blocked nose.

2. What you need to know before you take Ryaltris

Do not take Ryaltris

- 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.

Warnings and precautions

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.

Other medicines and Ryaltris

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

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.

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 to use Ryaltris

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

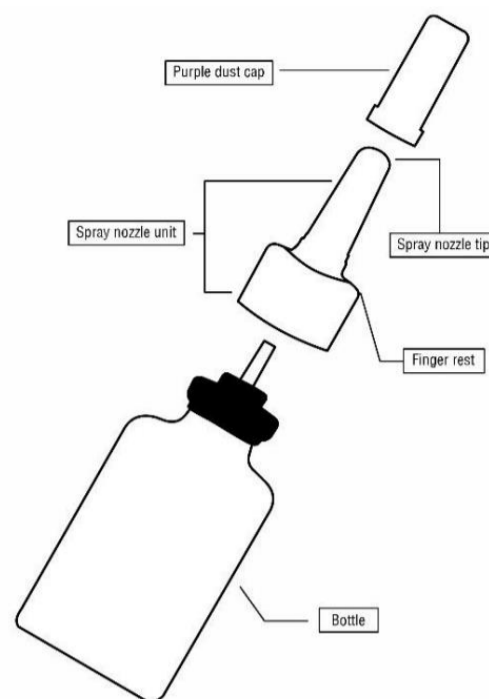
The spray is for nasal use.

Read the following instructions carefully and use only as directed.

Shake the bottle for minimum 10 seconds before each use.

When Ryaltris is not in use, the purple dust cap should always be kept tightly placed on the white nozzle tip.

Your Ryaltris nasal spray bottle



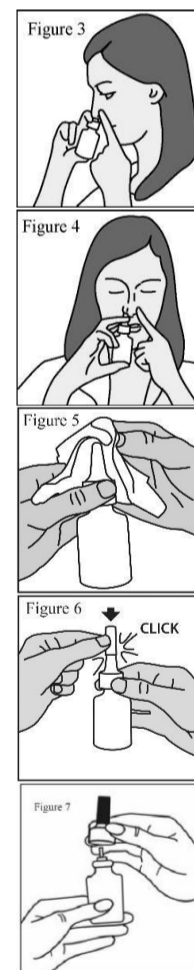
Preparing the nasal spray bottle

1. Shake the bottle for minimum 10 seconds and then remove the purple dust 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. Hold the nasal spray bottle firmly and upright with your index and middle finger on either side of the spray nozzle unit applicator (on finger rests) while supporting the grooved base of the bottle with your thumb.
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 shake the bottle well and "re-prime" the bottle by pumping the spray 2 times or 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. Hold the bottle firmly with your index and middle finger on either side of the spray nozzle unit (on finger rests) while supporting the grooved base of the bottle with your thumb.
4. 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).
5. Tilt your head forward slightly. Press down one time quickly and firmly on the finger rests to activate the pump.
6. Breathe in (inhale) gently through your nose as you spray. Then breathe out through your mouth (see figure 4).
7. Repeat the above steps and deliver a second spray in the same nostril.
8. Repeat with 2 sprays in the other nostril.
9. To prevent any blockage, after each use wipe the nozzle carefully with a clean dry tissue or cloth (see figure 5).
10. Hold the nozzle unit and push the purple dust cap back on the nozzle until 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 spray nozzle unit by gently pulling upward. (See Figure 7). Remove the purple dust cap and place only the spray nozzle unit in warm water to soak.
- **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.**
- After soaking the spray nozzle tip for 15 minutes, rinse the spray nozzle unit and purple dust cap with warm water and allow them to dry completely.
- Place the purple dust cap back on the spray nozzle tip and put it back on the bottle.
- After following the steps to clear your blocked spray nozzle tip see "**Preparing the nasal spray bottle**" section above and re-prime using 2 sprays. replace the purple dust cap, and your Ryaltris is ready for use.
- Repeat the unblocking steps if needed.

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.

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.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets 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 (may affect up to 1 in 10 people):

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

Uncommon (may affect up to 1 in 100 people):

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

Rare (may affect up to 1 in 1,000 people):

- 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.

Not known (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.

Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via HPRA Pharmacovigilance, Website: www.hpra.ie. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Ryaltris

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the bottle and carton after "EXP".

The expiry date refers to the last day of that month.

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. Contents of the pack and other information**What Ryaltris contains**

- The active substances are: mometasone furoate (as monohydrate) and olopatadine (as hydrochloride). One delivered dose (the dose that leaves the actuator) contains mometasone furoate monohydrate equivalent to 25 microgram mometasone furoate and olopatadine hydrochloride equivalent to 600 micrograms olopatadine.
- The other ingredients are: microcrystalline cellulose (E460), carmellose sodium (E 466), dibasic sodium phosphate heptahydrate (E 339), 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.

1 bottle of 30 ml with 240 actuations.

Manufacturer:

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

Product procured from within the EU, repackaged and distributed by the parallel product authorisation holder:

PCO Manufacturing Ltd., Unit 10, Ashbourne Business Park, Rath, Ashbourne, Co. Meath, Ireland.

Parallel Product Authorisation numbers: PPA0465/507/001

Ryaltis a registered trademark of the Glenmark Specialty S.A.

This medicinal product is authorised in the Member States of the EEA under the following names:

Austria, Belgium, Czechia, Denmark, Germany, Finland, France, Ireland, Italy, The Netherlands, Norway, Poland, Romania, Slovakia, Spain, Sweden: RYALTRIS

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