

Ryaltris[®] Nasal Spray Olopatadine Hydrochloride 600mcg/ mometasone furoate 25mcg

Olopatadine Hydrochloride and Mometasone Furoate (600mcg/25mcg)

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What RYALTRIS[®] is used for

RYALTRIS[®] is a prescription medicine used to treat symptoms of seasonal allergic rhinitis (also called “hay fever” caused by allergies to grass, pollen, ragweed, etc.) and perennial allergic rhinitis (year round allergies caused by dust mites, animal dander and molds) and related eye symptoms in patients 6 years of age and older.

How RYALTRIS[®] work

RYALTRIS[®] helps reduce the symptoms of seasonal and perennial allergic rhinitis (inflammation of the lining of the nose), such as stuffy nose, runny nose, nasal itching, sneezing, eye redness, itchy and watery eyes.

Before you use RYALTRIS[®]

- When you must not use it

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 such as cobicistat).

- If you are allergic to any of the ingredients in RYALTRIS[®].
- If you have untreated fungal, bacterial, or tuberculosis infections of the respiratory tract.

- Before you start to use it

To help avoid side effects and ensure proper use, talk to your healthcare professional before you take RYALTRIS[®]. Talk about any health conditions or problems you may have, including if you:

- Are pregnant (or planning to become pregnant). It is not known if RYALTRIS[®] will harm your unborn baby.
- Are breastfeeding or plan to breast-feed. It is not known if RYALTRIS[®] passes into your breast milk.
- Are allergic to any other corticosteroid or medications.
- Have green or yellow discharge from the nose.
- Have eye or vision problems, such as cataracts (clouding of the lens in the eye) or glaucoma (an increased pressure in your eyes).
- Are taking any other steroid medicine by mouth or as an injection.
- Are recovering from recent nasal surgery, nasal trauma or nasal ulcers.
- Have been near someone who has chickenpox or measles.
- Have a problem with your thyroid.
- Suffer from liver disease.

You should avoid coming into contact with measles or chickenpox while taking RYALTRIS[®]. If you are exposed, tell your doctor.

Drugs like RYALTRIS[®] can cause eye disorders:

- Cataracts: clouding of the lens in the eye, blurry vision, eye pain;
- Glaucoma: an increased pressure in your eyes, eye pain. If left untreated, it may lead to permanent vision loss.
- You should have regular eye exams.

Other warnings you should know about:

- RYALTRIS[®] can cause sleepiness or drowsiness. Do not drive, operate machinery, or do anything that needs you to be alert until you know how RYALTRIS[®] affects you.
- Do not drink alcohol or take any other medicines that may cause you to feel sleepy while using RYALTRIS[®].

- Taking other medicines

Tell your healthcare professional about all the medicines you take, including any drugs, vitamins, minerals, natural supplements or alternative medicines.

- Ketoconazole (for fungal infections)
- Ritonavir, cobicistat-containing products, atazanavir, indinavir, nelfinavir, or saquinavir (commonly used to treat HIV infection or AIDS)
- Clarithromycin (for bacterial infections)
- Itraconazole (for fungal infections)
- Nefazodone (antidepressant)
- Telithromycin (for pneumonia, an infection of the lungs).

How to use RYALTRIS[®]

RYALTRIS[®] is for use in your nose only. Do not spray it into your eyes or mouth. Use RYALTRIS[®] exactly as recommended by your healthcare provider.

Preparing the nasal spray bottle

Before you use RYALTRIS[®] for the first time, you will need to shake the bottle well and prime the pump.

Priming your RYALTRIS[®] pump before the first use

Before you prime the bottle, shake the bottle well.

Shake the container well before each use. The bottle should be discarded after the labelled number of actuations.

Diagram of RYALTRIS[®] nasal spray bottle (See Figure 1)

Note: The figures below are intended for illustrative purposes only. Thus, the product labels may not be representative of the actual drug product.

Figure 1



Step 1 - Remove the dust cap.

Remove the purple plastic dust cap from the spray pump tip of the bottle (See Figure 2).

Figure 2



Step 2 - Preparing the nasal spray bottle

- Hold the nasal spray bottle firmly and upright with your index and middle finger on either side of the applicator (on finger rests) while supporting the grooved base of the bottle with your thumb.
- Before first use, push down on the pump quickly and firmly 6 times, releasing the spray into the air, away from the eyes and face until a fine mist appears (See Figure 3).
- If you do not use RYALTRIS® for 14 days or more, you will need to shake the bottle well, and prime the pump with 2 sprays or until a fine mist appears.

Figure 3



Your RYALTRIS® is now ready for use.

Using your RYALTRIS®:

Step 3 -

Gently blow your nose to clear your nostrils (See Figure 4).

Figure 4



Step 4 - Using the nasal spray:

- Shake the bottle well before each use (morning and evening).
- Hold the bottle firmly with your index and middle finger on either side of the applicator (on finger rests) while supporting the grooved base of the bottle with your thumb (See Figure 5).

Figure 5



Hold 1 nostril closed with a finger. Insert the end of the nasal tip into the other nostril, pointing it slightly toward the outside of the nose, away from the nasal septum (the wall between the 2 nostrils) (See Figure 6).

Figure 6



- Tilt your head forward slightly. Keep the bottle upright, and press down once quickly and firmly on the finger rests to activate the pump. Breathe in (inhale) gently through your nose as you spray. Then breathe out through your mouth. (See Figure 7).
- Try not to get any spray in your eyes or directly on your nasal septum (the wall between the 2 nostrils).
- Children (6 to 11 years of age): Deliver 1 spray in each nostril.
- Adults and Adolescents (12 years of age and older): Deliver 2 sprays in each nostril.

Figure 7



- Avoid blowing your nose for the next 15 minutes to make sure RYALTRIS® gets a chance to work. Do not tip your head back right after using to keep the medicine from going into your throat.
- Each time after you finish using the medicine, wipe the tip with a clean dry tissue or cloth (See Figure 8).

Figure 8



While holding the spray pump unit, each time push the dust cap back on the spray tip of the bottle until a noticeable click is observed (See Figure 9).

Figure 9



How to clear the RYALTRIS® spray pump unit if it becomes clogged:

You must never attempt to unblock or enlarge the spray hole with a pin or other sharp objects because this will destroy the spray mechanism and you may not get the correct dose of medicine (see figure 10).

Figure 10



If the spray pump unit becomes blocked, remove it by gently pulling upward (See Figure 11).

Figure 11



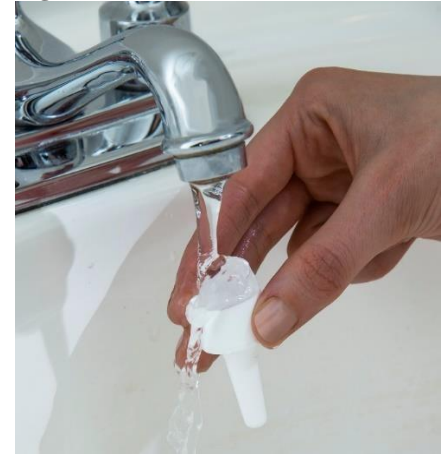
Remove the dust cap and place only the spray pump unit in warm water to soak (See Figure 12).

Figure 12



After soaking for approximately 15 minutes, rinse both ends with warm tap water for 1- 2 minutes, and allow them to dry completely (See Figure 13).

Figure 13



When dry, place the dust cap on the spray pump tip and put the spray pump unit back on the bottle (See Figure 14).

Figure 14



Following the unblocking procedure, review the “Priming your RYALTRIS® pump before use” section above and re-prime using 2 sprays. Replace the dust cap and your RYALTRIS® is ready for use.

Repeat the unblocking steps if needed. You should clean your nasal spray at least once a week to avoid it from getting blocked up. Additional cleaning is required when your spray becomes blocked.

Do not leave Ryaltris® openly in the car or at the office or home in a cold or hot weather.

Keep track of the number of days you use RYALTRIS® Even if the bottle seems to have medicine left in it, you may not receive the correct dose.

- How much to use

Adults and adolescents (12 years of age and older): 2 sprays in each nostril twice a day (morning and evening).

Children (6 to 11 years of age): 1 spray in each nostril twice a day (morning and evening).

- When to use it

RYALTRIS® relieves the symptoms within 10 minutes. However, you will get the best results if you keep using RYALTRIS® at regular intervals.

- How long to use it

As recommended by the Medical practitioner /physician.

- If you forget to use it

If you miss a dose, the next dose should be taken when it is due. Do not take a double dose.

- If you use too much (overdose)

With the nasal route of administration, overdose reactions are not anticipated.

If a child accidentally swallows RYALTRIS® or you use too much RYALTRIS®, call your doctor or go to the nearest hospital emergency room right away.

If you think you have taken too much RYALTRIS®, contact your healthcare professional, hospital emergency department or regional poison control centre immediately, even if there are no symptoms.

While you are using it

- Things you must do

Tell your doctor if you are pregnant or plan to become pregnant.
Tell your doctor if you plan to have or have had a recent nasal surgery or trauma.

- Things you must not do

Remember that your doctor has prescribed this medicine only for you. Never give it to anyone else.
RYALTRIS® is for intranasal use only.
Avoid getting it into your eyes. Do not use it to treat anything other than the condition for which it was prescribed.

- Things to be careful of

While using RYALTRIS®, avoid coming into contact with anyone who has measles or chickenpox. You should tell your doctor if you do come into contact with anyone who is suffering from these interactions.

Side effects

These are not all the possible side effects you may feel when taking RYALTRIS®.

Serious side effects and what to do about them

Symptom / effect

COMMON

- Nosebleeds- Talk to your healthcare professional, only if severe. Talk to your healthcare professional, in all cases Stop taking drug and get immediate medical help.
- Glaucoma: increased pressure in your eyes, eye pain.

If you have a troublesome symptom or side effect that is not listed here or becomes bad enough to interfere with your daily activities, talk to your healthcare professional.

You may report any side effects or adverse drug reactions or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by visiting the website npra.gov.my [Consumers → Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI)]

Storage and Disposal of RYALTRIS®

- Storage

Store upright with dust cap below 30°C. Do not freeze or refrigerate.

- Disposal

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

Product Description

- What it looks like

A printed carton containing a leaflet & a labelled white bottle containing a white homogenous suspension free of lumps, crimp-sealed with a nasal spray pump and fitted with a white actuator and purple overcap. The bottle is free of residue,

stains, cracks, dents, discolouration or flash or other visible defects.

- Ingredients

- Active Ingredients:

Olopatadine Hydrochloride
Mometasone Furoate Monohydrate

- Inactive ingredients:

Benzalkonium chloride,
carboxymethyl cellulose sodium,
Edetate disodium,
Hydrochloric acid,
Microcrystalline cellulose and
carboxymethyl cellulose sodium,
Polysorbate 80,
Sodium chloride,
Sodium hydroxide,
Dibasic Sodium Phosphate,
Heptahydrate,
Water for injection

- MAL number

Manufacturer

Glenmark Pharmaceuticals Ltd.
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Product Registration Holder

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Date of Revision

18 August 2022

Serial Number

NPRA (R1) 21/011.