

RYALTRIS[®] Nasal Spray

Consumer Medicine Information (CMI) summary

The [full CMI](#) on the next page has more details. If you are worried about using this medicine, speak to your doctor or pharmacist.

1. Why am I using RYALTRIS[®]?

RYALTRIS[®] is a combination treatment containing the active ingredients olopatadine hydrochloride and mometasone furoate monohydrate. RYALTRIS[®] is used to treat the symptoms of allergic rhinitis (hay fever or other year round allergies) including runny nose, sneezing, itchy or blocked nose and rhinoconjunctivitis symptoms relating to the eyes including itchy, burning and red eyes.

For more information, see Section [1. Why am I using RYALTRIS[®]?](#) in the full CMI.

2. What should I know before I use RYALTRIS[®]?

Do not use if you have ever had an allergic reaction to RYALTRIS[®] or any of the ingredients listed at the end of the CMI.

Talk to your doctor if you have any other medical conditions, take any other medicines, or are pregnant or plan to become pregnant or are breastfeeding.

For more information, see Section [2. What should I know before I use RYALTRIS[®]?](#) in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with RYALTRIS[®] and affect how it works.

A list of these medicines is in Section [3. What if I am taking other medicines?](#) in the full CMI.

4. How do I use RYALTRIS[®]?

- For adults and children 12 years and older, administer two sprays into each nostril twice daily (morning and evening).
- For Children 6 to 11 years, administer one spray into each nostril twice daily (morning and evening).

More instructions can be found in Section [4. How do I use RYALTRIS[®]?](#) in the full CMI.

5. What should I know while using RYALTRIS[®]?

Things you should do	<ul style="list-style-type: none">• Remind any doctor, dentist or pharmacist you visit that you are using RYALTRIS[®].• Tell your doctor or pharmacist if you become pregnant while using his medicine.• See your doctor or pharmacist immediately if you notice the symptoms of severe bacterial infection.
Things you should not do	<ul style="list-style-type: none">• Do not use this medicine to treat any other complaints unless your doctor tells you to.• Do not give this medicine to anyone else, even if they have the same condition as you.• Do not stop taking your medicine or lower the dosage without checking with your doctor.
Driving or using machines	<ul style="list-style-type: none">• RYALTRIS[®] can cause sleepiness or drowsiness.• Be careful before you drive or use any machines or tools until you know how RYALTRIS[®] affects you.
Drinking alcohol	<ul style="list-style-type: none">• Alcohol may cause you to feel sleepy while using RYALTRIS[®].
Looking after your medicine	<ul style="list-style-type: none">• Keep the nasal spray in a cool dry place where the temperature stays below 30°C.• Do not freeze or refrigerate. Store it away from heat.

For more information, see Section [5. What should I know while using RYALTRIS[®]?](#) in the full CMI.

6. Are there any side effects?

All medicines can have side effects. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention.

Common side effects include nasal problems (e.g. nasal discomfort, nosebleeds, crusting), unpleasant taste, and headache.

For more information, including what to do if you have any side effects, see Section [6. Are there any side effects?](#) in the full CMI.

RYALTRIS[®] Nasal Spray

(rye – al' – tris)

Active ingredient(s): *Olopatadine hydrochloride and mometasone furoate monohydrate*

Consumer Medicine Information (CMI)

This leaflet provides important information about using RYALTRIS[®]. **You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about using RYALTRIS[®].**

Where to find information in this leaflet:

- [1. Why am I using RYALTRIS[®]?](#)
- [2. What should I know before I use RYALTRIS[®]?](#)
- [3. What if I am taking other medicines?](#)
- [4. How do I use RYALTRIS[®]?](#)
- [5. What should I know while using RYALTRIS[®]?](#)
- [6. Are there any side effects?](#)
- [7. Product details](#)

1. Why am I using RYALTRIS[®]?

RYALTRIS[®] contains two active ingredients olopatadine hydrochloride and mometasone furoate monohydrate. Olopatadine hydrochloride is an antihistamine that reduces the effects of histamine, a natural chemical in the body. Histamine can make you sneeze, have itchy or watery eyes, and runny nose. Mometasone furoate monohydrate belongs to a family of medicines called corticosteroids, which are used to help reduce inflammation.

RYALTRIS[®] is used to treat the symptoms of allergic rhinitis (hay fever or other year round allergies such as pet, mould or dust allergies) and rhinoconjunctivitis (allergy defined by symptoms in the nose and eyes).

RYALTRIS[®] relieves symptoms of allergies, including stuffiness (congestion) in the nose, runny nose, itchy nose, sneezing, as well as watering, itching and redness of the eye.

2. What should I know before I use RYALTRIS[®]?

Warnings

Do not use RYALTRIS[®] if:

- you are allergic to olopatadine hydrochloride or mometasone furoate monohydrate, or any of the ingredients listed at the end of this leaflet.

Always check the ingredients to make sure you can use this medicine.

- you have a tendency to bleed or recurrent nose bleeding.
- you have severe nose infection, especially fungal infection.
- you have had recent nose injury or nose surgery; check with your doctor, because you may be told to wait until healing has occurred before using this medicine.

Check with your doctor or pharmacist if you:

- have any other medical conditions, especially the following:
 - history of tuberculosis, or active tuberculosis
 - tendency to bleed or recurrent nose bleeding
 - severe nose infection, especially fungal infection.
 - infection of the nose, sinus, mouth, throat, lungs or eye infection caused by herpes
 - sores in the nose
 - recent injury or surgery to your nose
 - non-allergic conditions affecting the inside of your nose, such as a deviated septum
 - eye or vision problems, such as cataracts or glaucoma (increased pressure in your eyes)
 - been near someone who has chickenpox or measles
 - not feeling well or have other symptoms that you do not understand
- take any medicines for any other condition
- have any other medical conditions.

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them. See additional information under Section [6. Are there any side effects?](#)

Pregnancy and breastfeeding

Check with your doctor or pharmacist if you are pregnant or intend to become pregnant.

Talk to your doctor or pharmacist if you are breastfeeding or intend to breastfeed.

Breastfeeding is not recommended during treatment with this medicine.

Use in Children

Do not give this medicine to a child under the age of 6 years.

Safety and effectiveness in children younger than 6 years have not been established. Safety in children 6 to 11 years of age has not been studied beyond 2 weeks.

3. What if I am taking other medicines?

Tell your doctor or pharmacist if you are taking

- other corticosteroid medicines, either by mouth, as eye drops, as an asthma inhaler or by injection, or;
- any other medicines, including any medicines, vitamins or supplements that you buy without a prescription from your pharmacy, supermarket or health food shop.

Some medicines may interfere with RYALTRIS® and affect how it works.

- Certain antifungals such as ketoconazole and itraconazole
- Some antibiotics such as clarithromycin
- Some medicines used to treat HIV infection such as ritonavir and cobicistat-containing products.

Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect RYALTRIS®.

4. How do I use RYALTRIS®?

How much to take / use

Adults and Children 12 years and older

- Two sprays into each nostril twice daily.

Children 6 to 11 years

- One spray into each nostril twice daily.

If symptoms worsen during treatment, see your doctor immediately.

When to take / use RYALTRIS®

- RYALTRIS® ALLERGY should be used twice daily (morning and evening).

How to use RYALTRIS®

Scan the QR code for a video on how to use this spray or clean a blocked nozzle.



About your nasal spray

Your RYALTRIS® ALLERGY nasal spray bottle (see Figure 1)

Figure 1



Priming your RYALTRIS® pump before first use (Step 1 and 2)

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

Before you prime the bottle, shake the bottle well.

Step 1. Remove the dust cap.

Shake the bottle well. 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 you use the bottle for the first time, 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)

Figure 3



- If you do not use RYALTRIS[®] for 14 or more days, you will need to shake the bottle well, and prime the pump with 2 sprays or until a fine mist appears.

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)

Figure 7



- Try not to get any spray in your eyes or directly on your nasal septum (the wall between the 2 nostrils).

- For adults and adolescents (12 years of age and older), repeat the above steps and deliver a second spray in the same nostril. Repeat with 2 sprays in the other nostril.
- 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 sure RYALTRIS[®], this will help keep the medicine from going into your throat.
- 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, push the dust cap back on the spray tip of the bottle until a noticeable click is observed to minimise potential nozzle blockage. (See Figure 9)

Figure 9



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

Do not try to unblock the spray pump unit by inserting a pin or other sharp object. This will damage the spray pump unit, and you may not get the correct dose of medicine.

If the spray pump unit becomes blocked, remove it by gently pulling upward. Remove the dust cap and place

only the spray pump unit in warm water to soak. (See Figure 10)

Figure 10



After soaking for approximately 15 minutes, rinse the spray pump unit and cap with warm tap water, and allow them to dry completely. (See Figure 11)

Figure 11



When dry, place the dust cap on the spray pump tip and put the spray pump unit back on the bottle. (See Figure 12)

Figure 12



Following the unblocking procedure, review the “Priming your 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.

If you forget to use RYALTRIS®

RYALTRIS® should be used regularly at the same time each day. If you miss your dose at the usual time, take it as soon as you remember, and then go back to using your medicine as you would normally.

If it is almost time for your next dose, skip the dose you missed and take your next dose when you are meant to.

Do not take a double dose to make up for the dose you missed.

If you are not sure what to do, ask your doctor or pharmacist.

If you use too much RYALTRIS®

If you think that you have used too much RYALTRIS®, you may need urgent medical attention.

You should immediately:

- phone the Poisons Information Centre (by calling 13 11 26), or
- contact your doctor, or
- go to the Emergency Department at your nearest hospital.

You should do this even if there are no signs of discomfort or poisoning.

5. What should I know while using RYALTRIS®?

Things you should do

If you become pregnant while you are using this medicine, tell your doctor or pharmacist.

See your doctor or pharmacist immediately if you notice the symptoms of severe bacterial infection. These symptoms may include fever, persistent face/tooth pain on one side of the face, swelling around the eye area, or worsening of symptoms after an initial improvement.

Remind any doctor, dentist or pharmacist you visit that you are using RYALTRIS®.

Things you should not do

- Do not use this medicine to treat any other complaints unless your doctor tells you to.
- Do not give this medicine to anyone else, even if they have the same condition as you.
- Do not stop taking your medicine or lower the dosage without checking with your doctor.

Driving or using machines

Be careful before you drive or use any machines or tools until you know how RYALTRIS® affects you.

RYALTRIS® can cause sleepiness or drowsiness.

Drinking

Tell your doctor or pharmacist if you drink alcohol.

Alcohol may cause you to feel sleepy while using RYALTRIS®.

Looking after your medicine

- Keep the nasal spray in a cool dry place where the temperature stays below 30°C.
- Do not freeze or refrigerate. Store it away from heat.

Follow the instructions in the carton on how to take care of your medicine properly.

Store it in a cool dry place away from moisture, heat or sunlight; for example, do not store it:

- in the bathroom or near a sink, or
- in the car or on window sills.

Keep it where young children cannot reach it.

When to discard your medicine

Keep track of the number of days you use RYALTRIS®. If you are using the 240-spray bottle, throw away the bottle after 240 sprays or upon expiration, whichever comes first.

Similarly, throw away the 120-spray bottle after 120 sprays.

If you are using the 56-spray bottle, throw it away after 56 sprays.

Even if the bottle seems to have medicine left in it, you may not receive the correct dose.

Do not count any sprays used for initial priming of the bottle.

Getting rid of any unwanted medicine

If you no longer need to use this medicine or it is out of date, take it to any pharmacy for safe disposal.

Do not use this medicine after the expiry date.

6. Are there any side effects?

All medicines can have side effects. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention.

See the information below and, if you need to, ask your doctor or pharmacist if you have any further questions.

Less serious side effects

Less serious side effects	What to do
<p>Nasal problems, which may include:</p> <ul style="list-style-type: none"> • crusting in the nose • nosebleeds • nasal discomfort <p>Unpleasant taste</p> <p>Headache</p> <p>Slow wound healing:</p> <ul style="list-style-type: none"> • You should not use RYALTRIS® until your nose has healed if you have a sore in your nose, if you have had surgery on your nose, or if your nose has been injured. <p>Thrush (<i>Candida</i>):</p> <ul style="list-style-type: none"> • a fungal infection in your nose and throat. Tell your healthcare provider if you have any redness or white-colored patches in your nose or mouth. 	<p>Speak to your doctor or pharmacist if you have any of these less serious side effects and they worry you.</p>

Serious side effects

Serious side effects	What to do
<ul style="list-style-type: none"> • Hole in the cartilage between your nose (nasal septal perforation). A whistling sound when you breathe may be a symptom of nasal septal perforation. • Symptoms of infection which may include fever, aches or pains, chills, feeling tired. • Symptoms of adrenal insufficiency which may include tiredness, weakness, nausea, vomiting, low blood pressure. • Blurred vision or increased pressure in your eye. • Sudden signs of allergy such as rash, itching or hives on the skin, swelling of the face, lips tongue or other parts of the body, wheezing or breathlessness. • Slowed or delayed growth in children. RYALTRIS® should not be given to children under the age of 6 years. A child's growth should be checked regularly while using intranasal corticosteroids. 	<p>Call your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you notice any of these serious side effects.</p>

Tell your doctor or pharmacist if you notice anything else that may be making you feel unwell.

Other side effects not listed here may occur in some people.

Reporting side effects

After you have received medical advice for any side effects you experience, you can report side effects to the Therapeutic Goods Administration online at www.tga.gov.au/reporting-problems. By reporting side effects, you can help provide more information on the safety of this medicine.

Always make sure you speak to your doctor or pharmacist before you decide to stop taking any of your medicines.

7. Product details

This medicine is available with a doctor's prescription.

What RYALTRIS® ALLERGY contains

Active ingredient (main ingredient)	Olopatadine hydrochloride Mometasone furoate monohydrate
Other ingredients (inactive ingredients)	Glycerol Carmellose sodium Dibasic sodium phosphate heptahydrate Disodium edetate Dispersible cellulose Hydrochloric acid Polysorbate 80 Sodium chloride Sodium hydroxide Water for injection
Potential allergens	Benzalkonium chloride

Do not take this medicine if you are allergic to any of these ingredients.

What RYALTRIS® looks like

RYALTRIS® is a white liquid suspension contained in a plastic bottle with a manual spray pump fitted with a white actuator and purple cap for intranasal administration (AUST R 473905).

Who distributes RYALTRIS®

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