SCHEDULING STATUS: S2

Namibia: NS3

RYALTRIS (nasal spray)

olopatadine and mometasone furoate

Read all of this leaflet carefully before you use RYALTRIS nasal spray:
- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor, pharmacist, nurse or other health care provider.
- **RYALTRIS** has been prescribed for you personally and you should not share your medicine with other people. It may harm them, even if their symptoms are the same as yours.

What is in this leaflet

1. What **RYALTRIS** is and what it is used for
2. What you need to know before you use **RYALTRIS**
3. How to use **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 olopatadine (which is an antihistamine medicine), and mometasone furoate (which is a corticosteroid).

RYALTRIS is sprayed into the nose to treat the symptoms of allergic rhinitis (hay fever or other year round allergies) and rhinoconjunctivitis (allergy induced 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 you need to know before you use RYALTRIS

Do not use RYALTRIS:
- If you are hypersensitive (allergic) to olopatadine hydrochloride, mometasone furoate, or any of the other ingredients of **RYALTRIS** (see **WHAT RYALTRIS CONTAINS**).
- If you are pregnant or breastfeeding your baby.
- If you have been or are going to be immunized with a live viral or bacterial vaccine.
- If you have active or dormant tuberculosis of your respiratory tract.
- If you have any untreated fungal, bacterial, viral or parasitic infections anywhere in or on your body.

Warnings and precautions

Tell your doctor or healthcare provider before using RYALTRIS

Special care should be taken with **RYALTRIS**:
- If you have been near someone who has chickenpox or measles. **RYALTRIS** may cause problems with the way your immune system protects your body against infection and increase your risk of infection. (see **POSSIBLE SIDE EFFECTS**). Avoid contact with people with contagious diseases.
- If you recently had nasal sores, nasal surgery, or nasal injury, you should not use **RYALTRIS** until your nose has healed.
- If you have eye or vision problems, such as cataracts or glaucoma (increased pressure in your eyes). You should have regular eye examinations when using **RYALTRIS**.
- If you are younger than 18 years of age, and still growing, as **RYALTRIS** can cause slowed or delayed growth in children. (see **POSSIBLE SIDE EFFECTS**).

Other medicines and RYALTRIS

Tell your doctor or pharmacist if you are using, have recently used or might use any other medicines.

Always tell your healthcare provider if you are taking any other medicine. (This includes all complementary or traditional medicines.)

Tell your doctor or pharmacist if you are currently taking:
- Other antihistamines (such as chlorphenamine, loratadine or cetirizine).
- Other medicines that are acting on the central nervous system (CNS), such as barbiturates (phenobarbital), benzodiazepines (diazepam), or opiates (morphine).
- Antifungal medicines, such as ketoconazole.

RYALTRIS with food or drink

Avoid alcohol while using **RYALTRIS**.

Pregnancy, breastfeeding, and fertility

If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist or other healthcare provider for advice before using **RYALTRIS**.

Pregnancy:

RYALTRIS should not be used by pregnant women.

Breastfeeding:

If you are breastfeeding you should not be using **RYALTRIS**.

Driving and using machines

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.

3. How to take RYALTRIS

Do not share medicines prescribed for you with any other person.

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

RYALTRIS is for use in your nose only. Do not spray it into your eyes or mouth.

The usual dose is 2 sprays into each nostril twice a day.

Components of RYALTRIS nasal spray:



Instructions for use:

Before you use **RYALTRIS**, make sure your healthcare provider shows you the right way to use it.

1. Shake the bottle well and remove the purple plastic over cap from the spray pump tip of the bottle (see **Figure 1**).



Figure 1

2. Priming your **RYALTRIS** pump before first use: 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 2**). If you don't use **RYALTRIS** for 14 days, you will need to shake the bottle well and prime the pump with two sprays or until a fine mist appears. Your **RYALTRIS** is now ready for use.



Figure 2

3. Gently blow your nose to clear your nostrils (see **Figure 3**).



Figure 3

4. 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 4**).



Figure 4

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 inside wall between the 2 nostrils) (see **Figure 5**).



Figure 5

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



Figure 6

7. Repeat the above steps 4 - 6 and deliver a second spray in the same nostril.
8. 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 to prevent **RYALTRIS** from going into your throat.
- After use, wipe the tip with a clean dry tissue or cloth (see **Figure 7**).



Figure 7

- Push the purple over cap back on the spray tip of the bottle, until a noticeable click sound is heard (see **Figure 8**).



Figure 8

- Each bottle of **RYALTRIS** contains enough medicine for 7 or 14 days of regular use (56 or 120 sprays after initial priming)

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 9**).



Figure 9

- 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 10**).



Figure 10

- When dry, place the dust cap on the spray pump tip and put the spray pump unit back on the bottle (see **Figure 11**).



Figure 11

- Following the unblocking procedure, review the *Priming your **RYALTRIS** pump before first use* (Step 2) above and re-prime using 2 sprays.
- Replace the over cap, and your **RYALTRIS** is ready for use.
- Repeat the unblocking steps if needed.

If you have the impression that the effect of **RYALTRIS** is too strong or too weak, tell your doctor or pharmacist. Your doctor will tell you how long your treatment with **RYALTRIS** will last.

If you use more RYALTRIS than you should:

In the event of overdosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison control centre.

Take this leaflet and the rest of the remaining nasal spray with you so the doctor will know what you have used.

If you forget to use RYALTRIS

If you have missed your dose by only a few hours, use the missed dose as soon as you remember. If it is almost time for your next dose, skip the missed dose and use **RYALTRIS** at the next regularly scheduled time.

Do not use a double dose of **RYALTRIS** to make up for the forgotten individual doses.

If you stop using RYALTRIS

In some patients **RYALTRIS** should begin to relieve symptoms 12 hours after the first dose; however full benefit of treatment may not be seen for up to two days. It is very important that you use your nasal spray regularly. Do not stop your treatment even if you feel better unless you are told to do so by your doctor.

4. Possible side effects

RYALTRIS can have side effects.

Not all side effects reported for **RYALTRIS** are included in this leaflet. Should your general health worsen or if you experience any untoward effects while using **RYALTRIS**, please consult your doctor, pharmacist or other healthcare professional for advice.

If any of the following happens, stop using **RYALTRIS** and tell your doctor immediately or go to the casualty department at your nearest hospital:
- Swelling of your hands, feet, ankles, face, lips, mouth or throat, which may cause difficulty in swallowing or breathing.
- Rash or itching.
- Fainting.

These are all very serious side effects. If you have them, you may have had a serious allergic reaction to **RYALTRIS**. You may need urgent medical attention or hospitalisation.

Tell your doctor immediately or go to the casualty department at your nearest hospital if you notice any of the following:
- Eye problems such as increase in pressure in the eye (glaucoma) and/or cataracts causing visual disturbances.
- Immune system problems that may increase your risk of infections (see **Take special care with RYALTRIS**). Symptoms of infection may include the following: fever, aches or pains, chills, feeling tired.
- Adrenal insufficiency (a condition in which the adrenal glands do not make enough steroid hormones). Symptoms of adrenal insufficiency may include the following: tiredness, weakness, nausea, vomiting, low blood pressure.
- Slowed or delayed growth (see **Take special care with RYALTRIS**).
- Nasal septal sore or perforation (a hole in the cartilage between your nose, causing a whistling sound when you breathe through your nose).

These are all serious side effects. You may need urgent medical attention.

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

Frequent:
- Unpleasant taste.
- Sleepiness or drowsiness.
- Anxiety or difficulty sleeping.
- Respiratory tract infections, inflammation at the back of the throat or tonsils.
- Throat irritation.
- Coughing, wheezing.
- Nasal dryness or discomfort.
- Dry mouth, stomach discomfort, vomiting.
- Red, inflamed, irritated or itching skin.

Less frequent:
- Red, itchy, irritable eyes.
- Diarrhoea, nausea, constipation.
- Headache.
- Fatigue.
- Nasal problems such as crusting in the nose, nosebleeds, runny nose.
- Slow wound healing.

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

Reporting of side effects

Reporting suspected adverse reactions after authorisation of the medicine is important. It allows continued monitoring of the benefit/ risk balance of the medicine. Health care providers are asked to report any suspected adverse reactions to SAHPRA via the "**6.04 Adverse Drug Reactions Reporting Form**", found online:
https://primaryreporting.who-umc.org/Reporting/Reporter

5. How to store RYALTRIS

Store at or below 25 °C.

Store upright with over cap. Do not freeze or refrigerate.

Do not use after the expiry date printed on the bottle label or outer carton.

STORE ALL MEDICINES OUT OF REACH OF CHILDREN.

Return all unused medicine to your pharmacist.

Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

6. Contents of the pack and other information

What RYALTRIS contains
- The active ingredients are olopatadine and mometasone furoate.
- The other ingredients are carboxymethyl cellulose sodium, dibasic sodium phosphate heptahydrate, edetate disodium, microcrystalline cellulose, polysorbate 80, sodium chloride, water for injection and benzalkonium chloride 0,02 % w/w.

What RYALTRIS looks like and contents of the pack

A white homogenous suspension free of lumps in a white opaque HDPE round bottle, crimp neck with base cap, having curved ribs at the bottom, crimp-sealed with a nasal spray pump and fitted with a white actuator and purple over cap and packed in an outer carton.

Each bottle contains 56 or 120 metered sprays depending on the pack size.

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This leaflet was last revised in
23 May 2022

Registration number

South Africa: 53/21.5.1/0457

Namibia: 20/32.2/0055

TO ACCESS THE PROFESSIONAL INFORMATION:
Please visit:

https://antcast.antfarm.co.za/videostreamingsolutions/Ryaltris