

PATIENT INFORMATION LEAFLET

SCHEDULING STATUS

S2

PROPRETARY NAME, STRENGTH AND PHARMACEUTICAL FORM

RINELON® Aqueous Nasal Spray

Pharmaceutical form: Metered dose bottle with manual spray pump for administration into the nostrils.

Active substance: Mometasone furoate monohydrate.

50 µg Mometasone furoate/spray.

Read all of this leaflet carefully, because it contains important information for you.

RINELON Aqueous Nasal Spray is available without a doctor's prescription, for you to treat a mild illness. Nevertheless you still need to use RINELON Aqueous Nasal Spray carefully to get the best results from it.

- Keep this leaflet. You may need to read it again.
- Do not share RINELON Aqueous Nasal Spray with any other person.
- Ask your pharmacist if you need more information or advice.
- You must see a doctor if your symptoms worsen or do not improve.

1. WHAT RINELON AQUEOUS NASAL SPRAY CONTAINS

The active substance is mometasone furoate monohydrate.

Each metered dose pump actuation delivers approximately 100 µg of mometasone furoate suspension, containing mometasone furoate monohydrate equivalent to 50 µg mometasone furoate.

The other ingredients are: Citric acid monohydrate, dispersible cellulose, glycerol, polysorbate 80, sodium citrate dihydrate and purified water.

Preservative: Benzalkonium chloride 0,02 % *m/m*

2. WHAT RINELON AQUEOUS NASAL SPRAY IS USED FOR

Pharmacotherapeutic group: Mometasone furoate is a cortisone-like medicine.

Therapeutic indications: RINELON Aqueous Nasal Spray is for use in adults, adolescents and children between the ages of 2 and 11 years to relieve symptoms that may occur with seasonal allergic hay fever or year-round nasal allergies, including stuffiness (congestion) in the nose, discharge, itching and sneezing.

Your doctor may also prescribe RINELON Aqueous Nasal Spray before the beginning of the pollen season to help prevent these symptoms.

3. BEFORE YOU USE RINELON AQUEOUS NASAL SPRAY

Do not use RINELON Aqueous Nasal Spray

- if you have ever had an allergic reaction to RINELON Aqueous Nasal Spray or to any of its ingredients. Tell your doctor so that he can give you another medicine.
- if you are pregnant or breastfeeding, as safety has not been established.
- in children under 2 years, as safety and efficacy have not been demonstrated.

Take special care with RINELON Aqueous Nasal Spray

RINELON Aqueous Nasal Spray should not be used

- if you have an infection in your nose that is not being treated.
- if you have recently had an operation on your nose or have injured your nose. You should wait until it has healed before you start using the nasal spray.

If you have any of the following conditions before treatment or develop them during treatment,

your doctor may need to reduce your dose of this medication, or you may need extra treatment to control them. Once advised, your doctor will decide whether any change in your treatment is needed. In some cases, it may be necessary to stop the treatment.

Before using RINELON Aqueous Nasal Spray, tell your doctor if you have any of the following disorders:

- recent nose injury or nose surgery
- sores in the nose
- tuberculosis (a history of, or active)
- infection (fungal, bacterial or viral)
- herpes simplex (virus) infection of the eye.

RINELON Aqueous Nasal Spray is a corticosteroid for nasal administration; it is not a restricted medicine for sports. Although it is not measurable in the blood, corticosteroid may be detected in the urine during drug testing, thus prior written permission for its use may be required by some sports agencies.

If you are pregnant or breastfeeding your baby while using this medicine, please contact your doctor, pharmacist or other healthcare professional for advice.

While using RINELON Aqueous Nasal Spray, avoid coming into contact with anyone who has measles or chickenpox. If you do, tell your doctor.

If you experience blurred vision or visual disturbances, contact your doctor.

Use this medicine exactly as your doctor or healthcare professional has instructed. Do not use more RINELON Aqueous Nasal Spray than recommended and do not use this medicine more often than recommended.

Do not share medicines prescribed for you with anyone else or use this product for other disorders.

If you think you are having an allergic reaction to RINELON Aqueous Nasal Spray (sudden onset of wheezing or difficulty in breathing shortly after taking this medication) seek medical assistance immediately.

With RINELON Aqueous Nasal Spray, especially with long-term use, the possibility of effects on the body must be considered.

Pregnancy and breastfeeding

If you are pregnant or breastfeeding your baby, please consult your doctor, pharmacist or other healthcare professional before using this medicine.

Safety in pregnancy and lactation has not been established.

Driving and using machinery: Not applicable.

Using other medicines with RINELON Aqueous Nasal Spray

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

4. HOW TO USE RINELON AQUEOUS NASAL SPRAY

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

Always use RINELON Aqueous Nasal Spray exactly as your doctor has instructed you. You should check with your doctor or pharmacist if you are unsure. If you have the impression that the effect of RINELON Aqueous Nasal Spray is too strong or too weak, talk to your doctor or pharmacist.

Method/Route of administration: For administration in the nostrils. Before each use: Blow your nose to clear the nasal passages. Shake container well.

RINELON Aqueous Nasal Spray must be primed before using for the first time. **Do Not** pierce the nasal applicator. To prime, press up and down on the pump 10 times until a fine spray appears. The pump is now ready for use. Tilt head downward then spray into each nostril as directed by your doctor. If the spray has not been used for 14 days or longer, prime the pump again with 2 actuations until a fine spray appears. Priming is not necessary when the spray is used daily.

The usual dose is:

Adults (including geriatric patients) and adolescents: 2 sprays (100 µg) into each nostril once daily (total dose 200 µg). When your symptoms have been controlled, your doctor may recommend 1 spray (50 µg/spray) into each nostril once daily (total dose 100 µg) to keep your symptoms under control. However, if you do not start to feel any better, you should see your doctor and he may change this dosage, depending on your response to RINELON Aqueous Nasal Spray. He may tell you to increase the dose to the maximum daily dose of 4 sprays into each nostril once a day. Once your symptoms are controlled, your doctor may advise you to reduce the dose to 2 sprays into each nostril once daily.

Children between the ages of 2 and 11 years: The usual recommended dose is 1 spray (50 µg/spray) into each nostril once daily (total dose 100 µg). Administration to young children should be aided by an adult.

Your doctor may change this dosage, depending on your response to RINELON Aqueous Nasal Spray.

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

Always follow your doctor's advice. Do not use a larger dose or use the spray more often or for longer than your doctor tells you to.

If you suffer badly from hay fever, your doctor may tell you to start using RINELON Aqueous Nasal Spray before the start of the pollen season, as this will help to prevent your hay fever symptoms from occurring. Your doctor may recommend that you use other treatments with RINELON Aqueous Nasal Spray, particularly if your eyes are itching or irritated. At the end of the pollen season your hay fever symptoms should get better and treatment may then not be needed.

If you are taking other corticosteroid medicines for allergy, either by mouth or injection, your doctor may advise you to stop taking them once you begin using RINELON Aqueous Nasal Spray. A few people may find that once they discontinue oral or injected corticosteroids they suffer from some undesirable effects, such as joint or muscular pain, weakness and depression. However, you should still continue using your nasal spray. You may also seem to develop other allergies, such as itchy, watering eyes or patches of red and itchy skin. If you develop any of these effects and you are worried, you should see your doctor.

About your nasal spray: Your RINELON Aqueous Nasal Spray has a dust cap, which protects the nozzle and keeps it clean. Remember to take this off before using the spray and to replace it after use.

It is important to clean your nasal spray regularly; otherwise it may not work properly.

Remove the dust cap and gently pull off the nozzle. Wash the nozzle and dust 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 to dry in a warm place. Push the nozzle back onto the bottle and replace the dust cap. The spray will need to be re-primed with 2 sprays when first used after cleaning.

At normal doses of 2 sprays into each nostril once daily, RINELON Aqueous Nasal Spray should provide enough doses for 35 days (18 g). If a bottle is not used up, it should be discarded 2 months after the first time you use it.

How to use your nasal spray:

1. Shake the bottle gently and remove the dust cap (**Figure 1**).



Figure 1

2. Gently blow your nose.
3. Close one nostril and put the nozzle into the other nostril as shown (**Figure 2**). Tilt your head forward slightly, keeping the bottle upright.



Figure 2

4. Start to breathe in gently or slowly through your nose and while you are breathing in, squirt a spray of fine mist into your nose by pressing down ONCE with your fingers.
5. Breathe out through your mouth. Adults and adolescents:
Repeat step 4 to inhale a second spray in the same nostril.
6. Remove the nozzle from this nostril and breathe out through the mouth.
7. Repeat steps 3 to 6 for the other nostril (**Figure 3**).

After using the spray, wipe the nozzle carefully with a clean handkerchief or tissue and replace the dust cap.



Figure 3

Frequency of administration: Once or twice daily. Do not use more frequently.

Duration of treatment: The length of treatment will be determined by your doctor.

If you use more RINELON Nasal Spray 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.

Although no unwanted effects are likely, contact your doctor or a healthcare professional as soon as possible.

If you forget a dose: If you forget to take your dose on time, take it as soon as possible, then go back to your regular dosing schedule. Do not double the dose.

Effects when treatment with RINELON Aqueous Nasal Spray is stopped: Not applicable.

5. POSSIBLE SIDE EFFECTS

RINELON Aqueous Nasal Spray can have side effects.

Not all side effects reported for RINELON Aqueous Nasal Spray are included in this leaflet.

Should your general health worsen or if you experience any untoward effects while using RINELON Aqueous Nasal Spray, please consult your doctor, pharmacist or other healthcare professional for advice.

If any of the following happens, stop using RINELON Aqueous Nasal Spray and tell your doctor immediately or go to the casualty department at your nearest hospital:

- Swelling of the face, lips, mouth or throat, which may cause difficulty in swallowing or breathing
- Rash or itching.

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

Tell your doctor if you notice any of the following:

- headache
- nose bleed or blood-tinged mucus
- burning or irritation inside the nose
- disturbances of taste and smell
- damage to the partition in the nose which separates the nostrils.
- increase in pressure in the eye (glaucoma), causing visual disturbances

- blurred vision
- sore throat
- sneezing
- skin rash.

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

6. STORING AND DISPOSAL OF RINELON AQUEOUS NASAL SPRAY

Store all medicines out of reach of children.

Store between 2 and 25 °C, away from heat. Do not freeze.

Check for signs of visible deterioration.

Do not use this product after the expiration date that appears on the package. If a bottle is not used up, it should be discarded 2 months after the first time you use it. Return any unused or expired medicines to your pharmacist. Do not dispose of unused medicines in drains and sewerage systems (e.g. toilets).

7. PRESENTATION OF RINELON AQUEOUS NASAL SPRAY

Packed in a 16,7 ml or 23,5 ml oval, white, opaque high density polyethylene bottle with a crimped-on metered dose pump assembly and a dust cover. Bottles containing 10 g (60 metered sprays) or 18 g (140 metered sprays) of nasal spray.

8. IDENTIFICATION OF RINELON AQUEOUS NASAL SPRAY

A white to off-white, opaque suspension.

9. REGISTRATION NUMBER

33/21.5.1/0482

10. NAME AND ADDRESS OF REGISTRATION HOLDER

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11. DATE OF PUBLICATION

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