PATIENT INFORMATION LEAFLET

Information for the Patient about

RHINIMET

SCHEDULING STATUS:

Schedule 2.

RHINIMET (mometasone furoate) Nasal Spray.

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

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

- Keep this leaflet. You may need to read it again.
- Do not share **RHINIMET** with any other person;
- If you have further questions, please ask your doctor or your pharmacist.

What is in this leaflet:

1. What RHINIMET is and what it is used for

2. What you need to know before you take RHINIMET

3. How to take RHINIMET

4. Possible side effects

5. How to store RHINIMET

6. Contents of the pack and other information

1. What RHINIMET is and what it is used for

RHINIMET contains mometasone furoate, one of a group of medicines called corticosteroids. When

RHINIMET is sprayed into the nose, it can help to relieve inflammation (swelling and irritation of the nose), sneezing, itching and a blocked up or runny nose.

RHINIMET Nasal Spray is used to treat hay fever in adults, adolescents and children aged 2 – 11 years.

Preventative treatment: **RHINIMET** Nasal Spray can be used as a preventative measure before the pollen season, for patients who have a history of moderate to severe hay fever.

2. WHAT YOU NEED TO KNOW BEFORE YOU USE RHINIMET

Do NOT use RHINIMET Nasal Spray:

- If you are hypersensitive (allergic) to mometasone furoate or any of the other ingredients of **RHINIMET** Nasal Spray**.**
- **RHINIMET** Nasal Spray should not be used during pregnancy and breastfeeding**.**
- **RHINIMET** Nasal Spray should not be used in children under 2 years of age.

Warnings and precautions

Take special care with RHINIMET Nasal Spray:

- Do not use **RHINIMET** Nasal Spray if you have an untreated infection involving the lining of the nasal cavity, such as herpes simplex (viral infection causing sores in the nose).
- Do not use **RHINIMET** Nasal Spray if you had recent nasal surgery or trauma as **RHINIMET** Nasal Spray may slow down the wound healing process. Wait until your wound is healed before starting **RHINIMET** Nasal Spray.
- Do not use **RHINIMET** Nasal Spray if you have a nasal septum perforation (hole in the nasal septum).

RHINIMET Nasal Spray should be used in caution:

- If you have or had tuberculosis.
- If you have an untreated fungal, bacterial or viral infection.
- If you have eye herpes (viral infection affecting the eye).
- If you are taking other corticosteroid medicine.
- If you are using **RHINIMET** Nasal Spray for several months your nasal lining should be examined regularly for possible changes. **RHINIMET** Nasal Spray should be stopped if inflammation of the nose or throat develops.
- If you are taking other corticosteroid medicines, either by mouth or injection whilst using **RHINIMET** Nasal Spray. If you stop using corticosteroid medicines, you may suffer from undesirable effects such as joint or muscle pain, lack of energy or depression.

Use in Children

The safety and efficacy of **RHINIMET** Nasal Spray in children under 2 years of age has not been established.

When used at high doses for long periods of time, corticosteroid nasal sprays may cause certain side-effects, such as slowed growth rate in children. It is recommended that the height of children receiving long-term treatment with nasal corticosteroids is regularly monitored and if any changes are noted, their doctor should be notified.

Other medicines and RHINIMET:

Always tell your healthcare professional if you are taking any other medicine.

(This includes complementary or traditional medicines.)

Please inform your health care provider if you are currently taking any of the following medicines listed below:

- Some medicines may increase the effects of **RHINIMET** and your doctor may wish to monitor you carefully if you are taking these medicines (e.g. medicines used to treat HIV such as ritonavir and cobicistat).

Pregnancy and breastfeeding:

If you are pregnant or breastfeeding your baby, think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist or other healthcare professional for advice before taking this medicine.

You should not take **RHINIMET** if you are pregnant or breastfeeding your baby.

There is no information about the use of **RHINIMET** Nasal Spray on fertility.

Driving or using machinery:

RHINIMET may make you feel dizzy. If **RHINIMET** affects you in this way do not drive, operate machinery or do anything that requires you to be alert.

It is not always possible to predict to what extent **RHINIMET** may interfere with your daily activities. You should ensure that you do not engage in the above activities until you are aware of the measure to which **RHINIMET** affects you.

RHINIMET contains benzalkonium chloride

RHINIMET Nasal Spray contains benzalkonium chloride (a preservative) which may cause nasal irritation.

3. HOW TO USE RHINIMET NASAL SPRAY:

Do not share medicines prescribed for you with any other person. Always use **RHINIMET** exactly as described in this leaflet or as your doctor, pharmacist or nurse have told you. Check with your doctor, pharmacist or nurse if you are not sure.

Hay fever

Adults and children over 12 years old: The usual recommended dose is two (2) sprays into each nostril once a day.

You may reduce the dose to one (1) spray in each nostril once your symptoms are under control.

If symptoms are not controlled you may increase the daily dose to a maximum of four (4) sprays in each nostril. You may reduce the dose once symptoms are under control.

Children between the ages of 2 and 11 years: One (1) spray in each nostril once a day which should be administered with the assistance of an adult.

If you have a history of moderate to severe hay fever; you may start using **RHINIMET** Nasal Spray a few days before the pollen season is expected to begin.

Method of administration

Shake container well before each use.

Priming

Upon first use you will be required to prime the nasal spray bottle.

Prime the bottle by spraying **RHINIMET** Nasal Spray 10 times until a uniform spray is formed.

If you have not used the nasal spray for more than 14 days you need to re-prime the bottle by pumping the spray until a uniform spray is formed.

How to use your **RHINIMET**:

1. Shake the bottle gently and remove the protective dust cap (see Diagram 1).

Diagram 1:



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

Diagram 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 (see Diagram 3).

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

Diagram 3:



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

If you use more RHINIMET 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.

If you forget to use RHINIMET Nasal Spray:

Do not take a double dose to make up for forgotten individual doses.

4. POSSIBLE SIDE-EFFECTS:

RHINIMET Nasal Spray may have side-effects.

Not all side-effects reported for RHINIMET Nasal Spray are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking this medicine, please consult your doctor, pharmacist or other healthcare professional for advice.

If any of the following happens, stop using **RHINIMET** and tell your doctor immediately or go to the casualty department at your nearest hospital:

- swelling of the hands, feet, ankles, face, lips and mouth or throat, which may cause difficulty in swallowing or breathing,
- rash.

These are all very serious side effects. If you have them, you may have had a serious reaction to **RHINIMET**. 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:

- difficulty breathing.

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

The following side effects are frequently associated with **RHINIMET** nasal spray**:**

- Sore throat
- Rhinitis
- Sinusitis
- Upper respiratory tract infection
- Dizziness and headache
- Bleeding from the nose
- Nasal burning, irritation, ulceration
- Throat irritation.

The frequency of the following side effects are unknown**:**

- Allergic reactions including swelling of the skin and trouble breathing
- Dry eyes, inflammation of the eyes, pressure in the eye, blurry vision
- Irritation to the wall that runs down the middle of the nose (nasal septum), runny nose, cough and holes in the nasal septum
- Changes to taste and smell and nausea
- Skin rash.

Children may experience the following side effects:

- bleeding from the nose
- headache
- nasal irritation

- sneezing.

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

Reporting of side effects

If you get side effects, talk to your doctor or, pharmacist or nurse. You can also report side effects to SAHPRA via the "**6.04 Adverse Drug Reaction Reporting Form**", found online under SAHPRA's publications: https://www.sahpra.org.za/Publications/Index/8.

Report all side effects to Unicorn Pharmaceuticals (Pty) Ltd to enquiries@unicornpharma.co.za

By reporting side effects, you can help provide more information on the safety of **RHINIMET.**

5. How to store RHINIMET nasal spray:

Store at or below 25 ºC.

Protect from heat.

Do not freeze.

Store in the original packaging.

Do not take after the expiry date stated on the package.

Return all unused **RHINIMET** Nasal Spray to your pharmacist.

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

KEEP OUT OF REACH OF CHILDREN.

6. CONTENTS OF THE PACK AND OTHER INFORMATION

What RHINIMET contains:

Each actuation delivers 100 mg **RHINIMET** Nasal Spray which contain 0,05175 mg mometasone furoate monohydrate equivalent to 0,050 mg mometasone furoate.

The other ingredients are benzalkonium chloride, citric acid monohydrate, glycerol, microcrystalline

cellulose – carmellose sodium, polysorbate 80, purified water and sodium citrate dehydrate.

What RHINIMET looks like and contents of the pack

White off homogenous aqueous suspension.

RHINIMET Nasal Spray is a metered dose nasal spray contained in white HDPE crimp on bottle, metered dose micro pump, nasal adaptor and transparent dust protective cap. This is packaged in a cardboard box.

Holder of Certificate of Registration

Unicorn Pharmaceuticals (Pty) Ltd

Corner of Searle and Pontac Streets

Cape Town

8001

Registration number(s)

52/21.5.1/0538

This leaflet was last revised in:

Not applicable