1.5.5 Proposed Patient Information Leaflet

Proposed PATIENT INFORMATION LEAFLET

SCHEDULING STATUS S2

RHINETON 4mg tablet

Chlorpheniramine maleate

Contains sugar: Lactose monohydrate 103,645 mg per tablet

Read all of this leaflet carefully before you start taking RHINETON

RHINETON is available without a doctor's prescription. Nevertheless, you still need to use RHINETON carefully to get the best results from it.

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

What is in this leaflet

1. What RHINETON is and what it is used for

RHINETON is used for the treatment of:

- perennial allergic rhinitis (allergy of the nose that is chronic and occurs year- round),

- seasonal allergic rhinitis (allergy of the nose that occurs acutely during specific times of the year),
- vasomotor rhinitis (allergy of the nose when the small blood vessels in the nose dilate causing nasal congestion),
- allergic conjunctivitis (inflammation of the lining of the eye due to allergy),
- allergic skin reaction (rash, itchiness, redness, bumps, swelling, hives),
- angioedema (swelling under the skin),
- severe allergic reactions,
- skin conditions such as eczema and atopic dermatitis (itchy inflammation of the skin),
- insect bites,
- drug reactions,
- itch associated with chickenpox.

2. What you need to know before you take RHINETON

Do not take RHINETON:

- if you are hypersensitive (allergic) to chlorpheniramine maleate or any of the ingredients of RHINETON (listed in section 6).
- if you are taking any Monoamine Oxidase Inhibitor (MAOI) medicines (for treatment of depression and panic disorders).

Warnings and precautions

Take special care with RHINETON:

- if you consume alcohol or other central nervous system depressants e.g. sedatives and tranquilizers (sleeping tablets and medicines which result in a calming effect). This may lead to drowsiness and impaired concentration.
- If you are going to drive a motor vehicle or operate machinery or perform potentially dangerous

tasks as RHINETON might lead to loss of concentration and accidents might occur.

- if you are going to be using RHINETON long term. This may cause decreased salivary flow and contribute to tooth decay, severe gum infection, and fungal infection in the mouth.
- if you suffer from increased pressure in the eye (glaucoma).
- if you suffer from stomach and duodenal ulcers (a sore that develops in the lining of the stomach and small intestine)
- if you suffer from an obstruction of the outlet of the stomach (pyloroduodenal obstruction).
- if you suffer from an prostatic hypertrophy (enlarged prostate).
- if you suffer from a bladder neck obstruction (bladder neck of the bladder fails to open adequately, resulting in obstruction of urinary flow).
- if you suffer from heart disease, including high blood pressure.
- if you suffer from an over active thyroid gland (hyperthyroidism).
- if you suffer from recurrent seizures (epilepsy).
- if you have a sudden asthma attack.
- if you are over 60 years of age. RHINETON may cause dizziness, drowsiness and low blood pressure.

Children and adolescents

Do not give RHINETON to children :

- if they have breathing problems such as chronic bronchitis.
- if they suffer from glaucoma (increase pressure in the eye).
- if they are taking sedatives and tranquilizers (medicines which result in a calming effect).

Other medicines and RHINETON

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

Tell your health care professional if you are taking any of the following medicines:

- sleeping tablets.
- alcohol.
- medicines that act as antidepressants.
- any medicines that stop the action of the enzyme Monoamine Oxidase (antidepressants).
- any medicines that stop the passage of certain nerve impulses involving acetyl choline (anticholinergics).
- any medicines that affect blood clotting (anticoagulants).
- before you have any skin tests for allergies, tell the doctor in charge that you are taking this medicine. The results of the test may be affected by this medicine.

Pregnancy, breast-feeding and fertility

The safety of RHINETON has not been studied in pregnant women.

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 health care provider for advice before taking this medicine.

Use is not recommended in nursing mothers, since babies are more susceptible to the side-effects of RHINETON, such as drowsiness, unusual excitement or irritability.

Driving and using machines

RHINETON may cause drowsiness and impair your concentration. Do not drive or operate machinery if you experience drowsiness, dizziness or blurred vision while taking RHINETON.

It is not always possible to predict to what extent RHINETON may interfere with the daily activities of a patient. Patients should ensure that they do not engage in the above activities until they are aware of the measure to which RHINETON affects them.

RHINETON contains lactose

RHINETON contains 103,645 mg of lactose monohydrate per tablet. This should be taken into account in patients with diabetes mellitus.

If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking RHINETON.

3. How to take RHINETON

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

Always take RHINETON exactly as described in this leaflet or as your doctor, pharmacist or nurse has told you. Check with your doctor, pharmacist or nurse if you are not sure.

Adults and children 12 years or older: One 4 mg RHINETON tablet every 4 to 6 hours, up to a maximum of 24 mg in 24 hours.

Children 6 to 12 years: 2 mg (Half a RHINETON tablet) every 4 to 6 hours, up to a maximum of 12 mg in 24 hours.

Children up to 6 years: Use is not recommended.

If you have the impression that the effect of RHINETON too strong or too weak, talk to your doctor or pharmacist.

If you take more RHINETON than you should

Overdosage may lead to death, especially in infants and children in whom the following symptoms may occur: ataxia (incoordination), excitement, hallucinations, muscle tremors, convulsions (seizures), dryness of mouth, dilated pupils (widened pupils), flushed or red face and extremely high fever. In adults, the usual symptoms are drowsiness, coma and convulsions (seizures). Low blood pressure may occur. Elderly patients are usually more sensitive to the effects of RHINETON.

In the event of overdosage, consult your doctor or pharmacist. If neither is available, seek

help at the nearest hospital or poison control centre.

If you forget to take RHINETON

Do not take a double dose to make up for a forgotten individual doses. If you forget to take a dose, take it as soon as you remember. If it is almost time for your next dose, do not take the dose that you missed.

If you stop taking RHINETON

Take RHINETON for as long as your doctor recommends. Don't stop unless your doctor advises you to.

4. Possible side effects

RHINETON can have side effects.

Not all side-effects reported for RHINETON are included in this leaflet.

Should your general health worsen or if you experience any untoward effects while taking RHINETON, please consult your health care provider for advice.

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

- allergic reactions can be severe. Signs include:
- raised and itchy rash (hives),
- swelling, sometimes of the face or mouth causing difficulty in breathing,
- collapse.

These are all very serious side effects. If you/your child have them, you/your child may have had a serious allergic reaction to RHINETON. You/your child 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:

- chest tightness
- hepatitis (liver disease), including jaundice (yellow pigmentation of skin and eyes)

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

Tell your doctor if you notice any of the following:

Frequent side effects

- sedation (calming or relaxing state)
- somnolence (sleepiness)
- disturbance in attention
- abnormal coordination
- dizziness
- headache
- blurred vision
- nausea (feeling that one is about to vomit)
- dry mouth
- fatigue
- wheezing

Side effects with an unknown frequency

- serious blood disorders
- anorexia (lack of appetite)
- fever
- chills
- increased sweating
- confusion
- double vision
- seizure

- incoordination
- tremors
- excitation
- inability to sleep
- irritability
- dryness of the mouth, nose and throat
- nightmares
- depression
- tinnitus (ringing in the ears)
- palpitations (rapid irregular action of the heart)
- tachycardia (increased heart rate)
- arrhythmias (irregular heart beat)
- hypotension (low blood pressure)
- thickening of bronchial secretions (secretions of lungs)
- vomiting (to be sick)
- constipation
- painful urination
- abdominal pain (stomach pain)
- diarrhea (frequent or loose watery stools)
- dyspepsia (heartburn or indigestion)
- exfoliative dermatitis (shedding of scaly dead skin)
- photosensitivity (sensitivity to light)
- muscle twitching
- muscle weakness
- urinary retention

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

5. How to store RHINETON

- Store all medicines out of reach of children.
- Store at or below 25 °C, protected from light.
- Do not store in bathrooms in order to protect from light.
- Do not take medicine after the expiry date stated on the label.
- 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 RHINETON contains

The active substance is chlorpheniramine maleate 4 mg per tablet.. The other ingredients are lactose monohydrate, magnesium stearate,

microcrystalline cellulose, purified talc, quinolone yellow lake, sodium lauryl sulphate.

What RHINETON looks like and contents of the pack

Yellow, round, biconvex tablet, with a diameter of 7,20 mm, and a score on the one side.

Contents of the pack:

Containers of 30, 100 and 1000 tablets. Patient ready packs of

different pack sizes.

Holder of Certificate of Registration

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