

PATIENT INFORMATION LEAFLET

SCHEDULING STATUS S2

RHINETON SYRUP 2 mg/5 ml

Chlorpheniramine maleate

Contains sugar: Liquid glucose 1,6 g per 5 ml

Preservatives:

Methyl hydroxybenzoate 0,12 % *m/v*

Propyl hydroxybenzoate 0,016 % *m/v*

Read all of this leaflet carefully before you start taking RHINETON SYRUP

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

- Keep this leaflet. You may need to read it again.
- Do not share RHINETON SYRUP 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 SYRUP is and what it is used for
2. What you need to know before you take RHINETON SYRUP
3. How to take RHINETON SYRUP
4. Possible side effects
5. How to store RHINETON SYRUP
6. Contents of the pack and other information

1. What RHINETON SYRUP is and what it is used for

Rhineton syrup is used to relieve or prevent the symptoms of hay fever and other types of allergy. Rhineton syrup may also be used to prevent cough.

2. What you need to know before you take RHINETON SYRUP

Do not take RHINETON SYRUP :

- If you are hypersensitive (allergic) to chlorpheniramine maleate or any of the other ingredients of Rhineton syrup (listed in section 6).
- If your child is a premature infant or neonate.
- If you are experiencing acute attacks of asthma.
- If you suffer from epilepsy (recurrent seizures or fits).

Warnings and precautions

Take special care with RHINETON SYRUP:

- If you have narrow angle glaucoma, urinary retention and prostatic hypertrophy.
- This medicine may cause some people to become drowsy or less alert than they are normally.
- Make sure you know how you react to Rhineton syrup before you drive, use machines, or do anything else that could be dangerous if you are not alert.
- Rhineton syrup may add to the effects of alcohol and other CNS depressants (medicines that slow down the nervous system, possibly causing drowsiness). Some examples of CNS depressants are sedatives, tranquilizers, or sleeping medicine; prescription pain medicine or narcotics; barbiturates; medicine for seizures; muscle relaxants; or anaesthetics, including some dental anaesthetics.
- Check with your doctor before taking any of the above while you are using this medicine.

Other medicines and RHINETON SYRUP

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

- Monoamine oxidase inhibitors, antimuscarinic drugs such as atropine and tricyclic antidepressants – *Side-effects, such as dryness of mouth, of antihistamines or anticholinergics may be more likely to occur.
- Central nervous system (CNS) depressants (medicines that cause drowsiness) – Effects, such as drowsiness, of CNS depressants including alcohol, barbiturates, hypnotics, opioid analgesics, anxiolytic sedatives and antipsychotics may be worsened.
- 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.

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

Talk to your doctor or pharmacist before taking this syrup if you are taking any prescribed medicines; particularly phenytoin (for epilepsy) or medicines for anxiety or to help you sleep.

Pregnancy, breast-feeding and fertility

The safety of Rhineton syrup has not been studied in pregnant women.

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

Driving and using machines

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

RHINETON SYRUP.

It is not always possible to predict to what extent RHINETON SYRUP 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 SYRUP affects them.

RHINETON SYRUP contains 1,6 g of liquid glucose per 5 ml.

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 RHINETON SYRUP

RHINETON SYRUP contains methyl hydroxybenzoate and propyl hydroxybenzoate which may cause allergic reactions (possibly delayed).

3. How to take RHINETON SYRUP

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

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

Adults

5 ml - 20 ml daily in divided doses.

Children

1-2 years

2,5 ml ($\frac{1}{2}$ medicine measure) orally twice daily.

2-5 years

2,5 ml ($\frac{1}{2}$ medicine measure) orally every 4 to 8 hours to a maximum of 15 ml daily.

6-12 years

5 ml (1 medicine measure) orally every 4 to 8 hours to a maximum of 30 ml daily.

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

If you take more RHINETON SYRUP 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 syrup. 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 SYRUP

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 SYRUP

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

4. Possible side effects

RHINETON SYRUP can have side effects.

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

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

If any of the following happens, stop taking RHINETON SYRUP 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 SYRUP. You/your child may need urgent medical attention or hospitalisation.

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

Side effects with an unknown frequency

- serious blood disorders
- allergic reactions
- angioedema
- anaphylactic reactions (sudden, life-threatening severe allergic reaction)
- anorexia (lack of appetite)
- confusion
- excitation
- irritability
- 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)
- abdominal pain (stomach pain)
- diarrhea (frequent or loose watery stools)
- dyspepsia (heartburn or indigestion)
- hepatitis (liver disease), including jaundice (yellow pigmentation of skin and eyes)
- exfoliative dermatitis (shedding of scaly dead skin)

- rash
- urticaria (allergic skin reaction)
- photosensitivity (sensitivity to light)
- muscle twitching
- muscle weakness
- urinary retention
- chest tightness

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 SYRUP.

5. How to store RHINETON SYRUP

- Store all medicines out of reach of children.
- Store at or below 25 °C in a cool place.
- Protect from light.
- Keep well closed.
- Do not refrigerate / freeze
- 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 SYRUP contains

The active substance is chlorpheniramine maleate 2 mg per 5 ml syrup.

The other ingredients are blackcurrant colour LS1904/18, citric acid anhydrous, glycerin, grape concord 1524, liquid glucose, methyl hydroxybenzoate (0,12 % *m/v*), propyl hydroxybenzoate (0,016 % *m/v*), purified water, raspberry red H1277, sodium cyclamate, sodium saccharin, xanthan gum.

What RHINETON SYRUP looks like and contents of the pack

A grape-red coloured syrup with a grape flavour.

Contents of the pack:

50ml and 100ml in long round amber PVC bottles, fitted with a white LDPE snap on cap.

50 ml, 100 ml and 200 ml amber glass bottles, fitted with a white Polypropylene screw on cap.

50 ml, 100 ml and 200 ml HDPE bottles, fitted with a white screw on cap.

Holder of Certificate of Registration

RANBAXY PHARMACEUTICALS (PTY) LTD.

14 LAUTRE ROAD

STORMILL EXT.1

ROODEPOORT 1724

SOUTH AFRICA

This leaflet was last revised in

10 November 2022

Registration numbers

41/5.7.1/0780

