PATIENT INFORMATION LEAFLET

SCHEDULING STATUS: S1

RHINETON NON DROWSY

Loratadine

Contains sugar: Lactose monohydrate 78,25 mg/tablet.

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

- **RHINETON NON DROWSY** is available without a doctor's prescription, for you to treat a mild illness. Nevertheless you still need to use **RHINETON NON DROWSY** carefully to get the best results from it.
- Keep this leaflet. You may need to read it again.
- Do not share **RHINETON NON DROWSY** with any other person.
- Ask your healthcare 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 NON DROWSY** is and what it is used for

2. What you need to know before you take **RHINETON NON DROWSY**

3. How to take **RHINETON NON DROWSY**

4. Possible side effects

5. How to store **RHINETON NON DROWSY**

6. Contents of the pack and other information

1. What RHINETON NON DROWSY is and what it is used for

RHINETON NON DROWSY belong to a class of medicines known as antihistamines.

Adults: RHINETON NON DROWSY relieve symptoms associated with perennial and /or seasonal allergic rhinitis (for example hay fever), such as sneezing, runny or itchy nose, and burning or itchy

eyes. RHINETON NON DROWSY may also be used to help relieve symptoms of chronic urticaria (itching and redness) which is often known as hives or nettle rash or other allergic skin disorders.

2. What you need to know before you take RHINETON NON DROWSY

Do not take RHINETON NON DROWSY if:

- you are hypersensitive (allergic) to loratadine or to any of the other ingredients of RHINETON NON DROWSY (listed in section 6).
- you are pregnant or breastfeeding.
- you are over 65 years of age.
- if your child is under 2 years of age as safety and effectiveness of RHINETON NON DROWSY have not been established.

Warnings and precautions

Take special care with RHINETON NON DROWSY if:

- you have liver disease **(see HOW TO TAKE RHINETON NON DROWSY**).
- RHINETON NON DROWSY are not known to have sedative effects. However, a small number of patients may experience sedation. This effect may be compounded if you take alcohol or other central nervous system depressants at the same time. It is therefore advisable to determine individual response before driving or performing complicated tasks.

RHINETON NON DROWSY should be stopped at least two days (48 hours) before skin testing procedures since it may interfere with the results.

The safe and effective use of RHINETON NON DROWSY in children under two years of age have not been established.

The use of RHINETON NON DROWSY has been associated with the risk of weight gain (see POSSIBLE SIDE EEFECTS)

Other medicines and RHINETON NON DROWSY

Always tell your health care provider if you are taking any other medicine. (This includes all

complementary or traditional medicines).

It is important to tell your doctor if you are taking:

- excessive amounts of alcohol
- cimetidine (medicine for ulcers)
- erythromycin (antibiotic)
- ketoconazole (antifungal)
- quinidine (medicine for irregular heartbeats)
- fluconazole (antifungal)
- fluoxetine (antidepressant)
- skin test (stop taking RHINETON NON DROWSY at least 48 hours before skin testing).
- Do not take RHINETON NON DROWSY with **o**ther medicines known to slow or stop liver metabolism until further studies can be undertaken.

RHINETON NON DROWSY with food or drink

RHINETON NON DROWSY can be taken with or without a meal.

RHINETON NON DROWSY have not been shown to add to the effects of an alcoholic drink. Avoid drinking excessive amounts of alcohol.

Pregnancy and breastfeeding

Do not take RHINETON NON DROWSY if you are pregnant or breastfeeding your baby.

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 health care provider for advice before taking this medicine.

Driving and using machines

RHINETON NON DROWSY lack significant sedative effects but may cause drowsiness in some people. This effect may be compounded by taking alcohol or other central nervous system depressants at the same time. Therefore, be careful before driving or operating machinery. You will know after the first few doses how RHINETON NON DROWSY affects you.

RHINETON NON DROWSY contains lactose monohydrate.

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

3. How to take RHINETON NON DROWSY

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

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

Adults: The usual dose is one RHINETON NON DROWSY by mouth once a day.

The tablets should be swallowed whole with water and may be taken with or without food.

Special dosage instructions for specific populations

Kidney and liver impairment

If you have severe liver or kidney problems, your doctor or pharmacist may advise you to take a dose of 5 mg (half a tablet) once a day or 10 mg (one tablet) every other day.

Elderly patients

Do not take you RHINETON NON DROWSY if you are over 65 years of age

Paediatric patients

Do not give RHINETON NON DROWSY to children under 2 years of age.

Duration of treatment

The duration of use depends on the type, duration and course of your complaints and is determined by your doctor or pharmacist.

If you take more RHINETON NON DROWSY than you should

See section 4 below for the possible side effects that you may experience.

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 or some tablets with you so your doctor will know what you have taken.

If you forget to take RHINETON NON DROWSY:

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 take a double dose to make up a forgotten dose.

4. Possible side effects

RHINETON NON DROWSY can have side effects.

Not all side effects reported for RHINETON NON DROWSY are included in this leaflet. Should your general health worsen, or if you experience any untoward effects while taking RHINETON NON DROWSY, please consult your health care provider for advice.

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

- difficulty in breathing,
- skin rash,
- swelling of the face, mouth, lips, neck, tongue or throat.

These are all very serious side effects. If you have them, you may have had a serious reaction to RHINETON NON DROWSY. 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:

- irregular or rapid heartbeat,
- yellowing of the skin and eyes, also called jaundice.

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

Tell your doctor if you notice any of the following:

The frequent side effects reported include:

- headache,
- nervousness,
- tiredness,
- drowsiness,
- increased appetite,
- difficulty sleeping.

Other less frequent side effects reported include:

- low blood pressure,
- tingling or numbness of the hands or feet,
- uncontrollable movements,
- dizziness,
- sweating, sleep disturbances, depression, trembling,
- nausea (feeling sick), upset stomach, vomiting,
- diarrhoea, stomach pain,
- loss of appetite,
- fits,
- ringing in the ears,
- dry mouth,
- liver problems, including jaundice or hepatitis,
- muscle pain,
- lower than normal number of platelets in your blood,
- hair loss,
- rash.

Unknown frequency:

- weight increase.

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, 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 NON DROWSY.

5. How to store RHINETON NON DROWSY

Store all medicines out of reach of children.

Store at or below 25 °C, protected from moisture in the original carton.

Do not store in a bathroom.

Do not take the medicine after the expiry date stated on the label / carton.

Return any unused tablets 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 NON DROWSY contains

The active substance of RHINETON NON DROWSY is loratadine.

Each tablet contains loratadine (micronized) 10 mg.

The other ingredients are lactose monohydrate, maize starch, pregelatinised maize starch and magnesium stearate.

What RHINETON NON DROWSY looks like and contents of the pack

White to off-white, uncoated, round, flat tablets with bevelled edges, debossed with 'R' on one side and '10' on the other.

Contents of the pack:

Blister strips of clear, colourless PVC/PVDC film with aluminium foil backing containing 10 tablets. Cartons contain 10 and 30 tablets.

Holder of Certificate of Registration

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