PATIENT INFORMATION LEAFLET

SCHEDULING STATUS: **S2**

RUPANASE 10, tablets.

Rupatadine

Contains sugar (lactose monohydrate 61,100 mg per tablet)

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

RUPANASE 10 is available without a doctor's prescription, for you to treat a mild illness. Nevertheless you still need to use RUPANASE 10 carefully to get the best results from it.

- Keep this leaflet. You may need to read it again.
- Do not share RUPANASE 10 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 RUPANASE 10 is and what it is used for
2. What you need to know before you take RUPANASE 10
3. How to take RUPANASE 10
4. Possible side effects
5. How to store RUPANASE 10
6. Contents of the pack and other information

1. What RUPANASE 10 is and what it is used for

RUPANASE 10 relieves symptoms of allergic rhinitis such as sneezing, runny nose, itching in the eyes and nose.

RUPANASE 10 is also used to relieve symptoms associated with urticaria (an allergic skin rash) such as itching and hives (localised skin redness and swelling.)

2. What you need to know before you take RUPANASE 10

Do not take RUPANASE 10:

- if you are hypersensitive (allergic) to rupatadine or any of the other ingredients of RUPANASE 10 (listed in section 6).
- RUPANASE 10 is not recommended for use in children below 12 years of age.
- if you are pregnant or breastfeeding.

Warnings and precautions

Take special care with RUPANASE 10:

- If you have, or have had liver or kidney disease, ask your doctor for advice. The use of RUPANASE 10 is not recommended in patients with impaired kidney or liver functions.
- If you have a heart condition characterised by prolongation or a longer period of the QT interval which means the time between the Q wave and the end of the T wave in the heart's electrical cycle
- If you have uncorrected low potassium levels
- If you have a heart condition characterised by a significant slow heart rate
- If you have acute decreased blood flow to your heart
- If you are older than 65 years.

You should exercise caution if you are taking RUPANASE 10 with the following:

- grapefruit juice
- moderate CYP3A4 inhibitors (e.g. amiodarone, erythromycin, fluconazole, miconazole, diltiazem, verapamil)
- simvastatin, lovastatin, ciclosporin, tacrolimus, sirolimus, everolimus, cisapride.

Children

RUPANASE 10 is not recommended for use in children below 12 years of age.

Other medicines and RUPANASE 10

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

The following medicine can affect the action of RUPANASE 10:

- Antifungal medicine (fluconazole, itraconazole, ketoconazole, voriconazole)
- HIV medicine called saquinavir, indinavir, ritonavir, lopinavir)
- Antibiotics called erythromycin, clarithromycin

RUPANASE 10 can affect the action of the following medicine:

- Certain medicine where a small dosage adjustment can have severe effects (e.g., digoxin, phenytoin, phenobarbital, rifampicin, theophylline and warfarin)
- High cholesterol medicine belonging to the statin group (e.g. atorvastatin, simvastatin)
- Midazolam (sedative)

RUPANASE 10 with food and drink

- Can be taken with or without food and drink.
- It is recommended to avoid intake of grapefruit juice along with RUPANASE 10.
- It is not advisable to use alcohol concomitant with RUPANASE 10.

Pregnancy, breastfeeding and fertility

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 healthcare provider for advice before taking this medicine.

The use of RUPANASE 10 is contraindicated during pregnancy and breastfeeding.

Driving and using machines

At recommended doses, RUPANASE 10 is not expected to influence your ability to drive or use machinery. However, when you first start taking RUPANASE 10 you should take care to see how the treatment affects you before driving or using machinery.

It is not always possible to predict to what extent RUPANASE 10 may interfere with your daily activities. You should ensure that you do not engage in driving a vehicle or use machines until you are aware of the measure to which RUPANASE 10 affects you.

RUPANASE 10 contains lactose.

If you have been told by your doctor that you have intolerance to some sugars, contact your doctor before taking RUPANASE 10.

3. How to take RUPANASE 10

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

Always take RUPANASE 10 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.

The usual dose is:

Adults and adolescents (over 12 years of age) is: 10 mg (one tablet) once a day with or without food.

If you have the impression that the effect of RUPANASE 10 is too strong or too weak, tell your doctor or pharmacist.

Swallow RUPANASE 10 with a glass of water.

If you take more RUPANASE 10 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 take RUPANASE 10

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

If you stop taking RUPANASE 10

Your symptoms of your allergy may become worse or return if you stop your treatment.

4. Possible side effects

RUPANASE 10 can have side effects.

Not all side effects reported for RUPANASE 10 are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking RUPANASE 10, please consult your healthcare provider for advice.

If any of the following happens, stop taking RUPANASE 10 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 or itching
- fainting

These are all very serious side effects. If you have them, you may have had a serious reaction to RUPANASE 10. 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:

Less frequent

- nose bleeding, rash, muscle pain.
- back pain, stiffness in the joints
- fatigue, and lack of energy.

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

Tell your doctor if you notice any of the following:

Frequent

- dry mouth, feeling tired,
- somnolence, headache, dizziness

Less frequent

- sore throat

- runny nose
- abnormal liver function tests
- weight increase
- nasal dryness
- upper respiratory disorders
- cough, dry throat
- disturbance in attention
- nausea, upper abdominal pain
- diarrhoea
- dyspepsia
- vomiting
- abdominal pain
- constipation
- increased appetite
- thirst
- malaise
- pyrexia
- irritability

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 RUPANASE 10.

5. How to store RUPANASE 10

Keep the blister in the outer carton in order to protect from light.

Store at or below 30 °C and protect from light.

KEEP OUT OF THE REACH OF CHILDREN.

6. Contents of the pack and other information

What RUPANASE 10 contains

The active substance is rupatadine fumarate 12,80 mg equivalent to rupatadine 10 mg base.

The other ingredients are cellulose-microcrystalline, lactose monohydrate, magnesium stearate, pregelatinised maize starch, red iron oxide (E-172) and yellow iron oxide (E-172).

What RUPANASE 10 looks like and contents of the pack

RUPANASE 10 tablets are round, biconvex, light salmon pink in colour with no markings.

RUPANASE 10 tablets are packed in the following:

PVC-PVDC foil and aluminium blister packaging.

In pack sizes of 10 (1 strip of 10 tablets), 20 (2 strips of 10 tablets) or 30 (2 strips of 15 tablets) in a cardboard carton.

Holder of Certificate of Registration

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