PATIENT INFORMATION LEAFLET

SCHEDULING STATUS: S2

RAPUTEZE™, tablets

Rupatadine

Contains sugar (lactose monohydrate 38 mg per tablet)

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

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

- Keep this leaflet. You may need to read it again.
- Do not share RAPUTEZE with any other person.
- Ask your healthcare provider or pharmacist if you need more information or advice.

What is in this leaflet

1. What RAPUTEZE is and what it is used for
2. What you need to know before you take RAPUTEZE
3. How to take RAPUTEZE
4. Possible side effects
5. How to store RAPUTEZE
6. Contents of the pack and other information

1. What RAPUTEZE is and what it is used for

The active ingredient, rupatadine, is an antihistamine.

RAPUTEZE is used to relieve symptoms in adults and adolescents (over 12 years of age) of:

- allergic rhinitis (sneezing, runny nose, itching in the eyes and nose);

- urticaria (an allergic skin rash) such as itching and hives (localised skin redness and swelling).

2. What you need to know before you take RAPUTEZE

Do not take RAPUTEZE:

- if you are hypersensitive (allergic) to rupatadine or any of the ingredients of RAPUTEZE (listed in section 6);
- if you are younger than 12 years of age;
- if you are pregnant or breastfeeding your baby.

Warnings and precautions

Take special care with RAPUTEZE:

- if you have, or have had liver or kidney disease, ask your doctor for advice. The use of RAPUTEZE is not recommended in patients with impaired kidney or liver functions;
- if you have heart conditions or low potassium blood levels, talk to your doctor or pharmacist, as RAPUTEZE can worsen these conditions;
- if you are over the age of 65 years, as you can be more sensitive and can experience side effects.

Children

RAPUTEZE tablets are not recommended in children less than 12 years, as safety has not been established (see “Do not take RAPUTEZE”).

Other medicines and RAPUTEZE

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

Tell your doctor or pharmacist if you are taking any of the following:

- medicines used to treat infections, e.g., itraconazole, ketoconazole, voriconazole, posaconazole, erythromycin, fluconazole, clarithromycin as these medicines may enhance the concentration of rupatadine, contained in RAPUTEZE, in your body;
- medicines used for treatment of HIV e.g., saquinavir, indinavir, ritonavir, nelfinavir, amprenavir, fosamprenavir as these medicines may enhance the concentration of rupatadine, contained in RAPUTEZE, in your body;
- nefazodone (medicines used to treat depression), as it may enhance the concentration of rupatadine in your body;
- diltiazem (a medicine used to treat certain heart conditions), as it may enhance the concentration of rupatadine in your body;
- CNS depressants (medicines such as midazolam, to treat anxiety, panic attacks and acute stress reactions and sleep disorders), or alcohol, as RAPUTEZE may enhance their sedative effects if taken together. See below “RAPUTEZE with food, drink and alcohol”;
- statins (medicines to help lower cholesterol levels in the blood).

RAPUTEZE with food, drink and alcohol

Do not take RAPUTEZE with grapefruit juice as it enhances the effect of RAPUTEZE.

Pregnancy, breastfeeding and fertility

Do not take RAPUTEZE if you are pregnant or breastfeeding your baby (see “Do not take RAPUTEZE”).

The effect of RAPUTEZE on fertility is not known.

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.

Driving and using machines

RAPUTEZE causes sleepiness (somnolence) and dizziness.

It is not always possible to predict to what extent RAPUTEZE may interfere with your daily activities. However, when you first start taking RAPUTEZE you should take care to see how the treatment affects you before driving or using machinery.

RAPUTEZE contains lactose

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

3. How to take RAPUTEZE

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

Always take use RAPUTEZE exactly as described in this leaflet or as your doctor or pharmacist have told you. Check with your doctor or pharmacist if you are not sure.

RAPUTEZE is for adolescents (from 12 years and older) and adults.

The usual dose is one 10 mg tablet daily.

Take the tablet at the same time of day orally, with a glass of water.

RAPUTEZE can be taken with or without food.

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

If you take more RAPUTEZE than you should

In the event of overdosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison centre.

If you forget to take RAPUTEZE

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

If it is almost time for your next dose, skip the missed dose and take your next dose when you are meant to. Otherwise, take it as soon as you remember, and then go back to taking your tablets at your normal time.

If you are not sure if you should skip the dose, talk to your doctor or pharmacist.

4. Possible side effects

RAPUTEZE can have side effects.

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

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

- swelling of the mouth, tongue, face and/or throat, which may cause difficulty in swallowing or breathing,
- rash, hives (swelling, redness and itchiness of the skin),

These are all very serious side effects. If you have them, you may have had a serious reaction to RAPUTEZE. You may need urgent medical attention or hospitalisation.

Tell your doctor if you notice any of the following:

Frequent side effects:

- Sleepiness
- Headache
- Dizziness
- Dry mouth
- Sensation of weakness and fatigue

Less frequent side effects

- Sore throat, runny nose
- Increased appetite

- Irritability
- Difficulty concentrating
- Rapid or irregular heartbeat
- Nosebleed, nasal dryness
- Cough, dry throat, sore throat, pain in tonsils area
- Nausea, stomach pain, diarrhoea, indigestion, vomiting, constipation
- Rash
- Back pain, joint pain, muscle pain
- Thirst, general discomfort, fever
- Changes in some laboratory tests

Frequency unknown

- Disorientation
- Tremor
- Increased sweating
- Unable to walk in the normal way
- Redness of the eye and eyelid, blisters on the eyelid
- Redness of the skin or mucous membranes
- Redness of the genitals

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 Med Safety APP (Medsafety X SAHPRA) and eReporting

platform (who-umc.org) found on SAHPRA website. By reporting side effects, you can help provide more information on the safety of RAPUTEZE.

5. How to store RAPUTEZE

Store all medicines out of reach of children.

Store at or below 25 °C.

Store the blister in the original container until required for use.

Do not store in a bathroom.

Do not use after the expiry date stated on the blister/carton.

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 RAPUTEZE contains

- The active substance is rupatadine. Each tablet contains 10 mg of rupatadine (as rupatadine fumarate).
- The other ingredients are: lactose monohydrate (see section 2), microcrystalline cellulose PH 102 (E460), pregelatinised maize starch, colour iron oxide red (E 172), colour iron oxide yellow (E 172), magnesium stearate.

What RAPUTEZE looks like and contents of the pack

RAPUTEZE tablets are light-salmon coloured and round, with a diameter of approximately 6,35 mm.

Thermoformed blisters made of clear PVC (250 µm)/PVDC (40 g/m^2) and aluminium foil (25 µm).

Blisters are packed in a carton in pack sizes of 10, 20 or 30 tablets.

Not all pack sizes are necessarily marketed.

Holder of Certificate of Registration

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Access to the corresponding Professional Information

For the Professional Information (PI), please refer to https://medsinfo.sahpra.org.za/home.