Clean Amended Patient Information Leaflet for Medicines for Human Use:

RUTARN 10

SCHEDULING STATUS: S2

RUTARN 10 TABLETS

Rupatadine Fumarate

Contains sugar (lactose monohydrate)

Each 10 mg tablet contains 38,0 mg of lactose monohydrate

Read all of this leaflet carefully before you start taking RUTARN 10

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

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

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

RUTARN 10 is an antihistamine.

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

RUTARN 10 is also used to relieve the 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 RUTARN 10

Do not take RUTARN 10

- if you are hypersensitive (allergic) to rupatadine or any of the other ingredients of RUTARN 10 (listed in section 6)
- if you are pregnant or breastfeeding.

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

Warnings and precautions

Take special care with RUTARN 10

- if you suffer from kidney or liver insufficiency, ask your health care provider for advice. The use of RUTARN 10 is at present not recommended in patients with impaired kidney or liver functions
- if you have low blood levels of potassium and/or if you have a certain abnormal pattern to your heartbeat (known prolongation of the QT interval on the ECG) which can occur in some forms of heart disease, ask your health care provider for advice
- if you are older than 65, ask your health care provider.

Children and adolescents

This medicine is not for use in children under 12 years of age.

Other medicines and RUTARN 10

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

If you are taking RUTARN 10 do not take the following medicines:

- Ketoconazole, itraconazole, voriconazole, posaconazole, fluconazole (used for fungal infections),
- Erythromycin, clarithromycin (used for bacterial infections),
- Diltiazem (used for high blood pressure),
- Nefazodone (used to treat depression),
- Atazanavir, darunavir (used to treat HIV infection),
- Statins such as simvastatin, lovastatin (used to lower cholesterol)

RUTARN10 with food, drink and alcohol

RUTARN10 should not be taken in combination with grapefruit juice, as this may increase the level of rupatadine in your body.

RUTARN 10, at recommended dose (10 mg), does not increase the drowsiness produced by alcohol. Nonetheless, caution should be taken when co-administered.

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 health care provider for advice before taking this medicine.

Do not take RUTARN 10 if you are pregnant or breastfeeding.

Driving and using machines

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

It is not always possible to predict to what extent RUTARN 10 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 RUTARN 10 affects them.

RUTARN 10 contains lactose

If you have been told by your health care provider that you have intolerance to some sugars, you should contact your health care provider before taking RUTARN 10.

3. How to take RUTARN 10

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

Always take RUTARN 10 tablets exactly as prescribed in the leaflet or as your doctor or pharmacist or nurse has told you. Check with your doctor or pharmacist or nurse if you are not sure.

RUTARN 10 is for adults and adolescents (from 12 years and older). The usual dose is one tablet (10 mg) once daily.

Method of administration

You can take RUTARN 10 with or without food.

Swallow the tablets with sufficient quantity of liquid (e.g. one glass of water)

If you take more RUTARN 10 than you should

In the event of overdosage, consult your health care provider. If neither is available, contact the nearest hospital or poison centre.

If you forget to take RUTARN 10

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

If you forget to take a dose, leave that dose out completely. Take your next dose at the right time and continue as before.

4. Possible side effects

RUTARN 10 can have side effects.

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

Tell your health care provider if you notice any of the following:

Frequent side effects:

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

- Fatigue

Less frequent side effects:

- Increased appetite
- Irritability
- Difficulty concentrating
- Nosebleed
- Nasal dryness
- Sore throat, cough, dry throat
- Rhinitis
- Nausea, vomiting
- Abdominal pain
- Diarrhoea
- Indigestion
- Constipation
- Rash
- Back pain, joint pain, muscle pain
- Thirst
- General discomfort
- Fever
- Abnormal liver function test
- Increased weight
- Palpitations, increased heart rate
- Allergic reactions (itching, hives and swelling of the face, lips, tongue or throat).

If you notice any side effects not mentioned in this leaflet, please inform your health care provider.

Reporting of side effects

If you get side effects, talk to your health care provider. 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 RUTARN 10**.**
Suspected side effects can also be reported directly to the Holder of the Certificate of Registration via medsafety@austell.co.za.

5. How to store RUTARN 10

- Store all medicines out of reach of children.
- Store at or below 25 °C.
- Do not use this medicine after the expiry date which is stated on the carton after EXP. The expiry date refers to the last day of the month.
- 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 RUTARN 10 contains

The active substance is rupatadine.

Each tablet contains 10 mg of rupatadine.

The other ingredients are iron oxide red (E172), iron oxide yellow (E172), lactose monohydrate, magnesium stearate, microcrystalline cellulose ([~~ph~~] pH 102), starch pregelatinised (maize)

What RUTARN 10 looks like and contents of the pack

RUTARN 10 are light-salmon round tablets.

RUTARN 10 is packed in thermoformed blisters made of aluminium and PVC/PVdC clear film.

Pack of 10, 20 or 30 tablets in a cardboard box.

Not all pack sizes may be marketed.

Holder of Certificate of Registration

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Access to the corresponding Professional Information

Professional Information for this medicine is available on the following URL:

https://austell.co.za/product-info/

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