PATIENT INFORMATION LEAFLET

SCHEDULING STATUS S2

RAZTROL 10 mg TABLETS

(Rupatadine)

Contains sugar: lactose monohydrate 60 mg per tablet

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

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

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

1. What RAZTROL is and what it is used for

Rupatadine is an antihistamine.

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

Rupatadine 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 RAZTROL

Do not take RAZTROL

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

Rupatadine tablets are not recommended for use in children below 12 years of age.

Warnings and precautions

Take special care with RAZTROL:

- If you suffer from kidney or liver insufficiency, ask your doctor for advice. The use of rupatadine is 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 doctor for advice;
- If you are older than 65, ask your doctor or your pharmacist.

Children

Do not give RAZTROL to children below 12 years of age because it is unlikely to be safe.

Other medicines and RAZTROL

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

If you are taking RAZTROL do not take 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),
- Immunosuppressant such as ciclosporin, tacrolimus, sirolimus, everolimus (used in organ transplants to prevent rejection),
- Cisapride (used for heartburn).

Ask your doctor for advice before taking any medicine.

RAZTROL with food, drink and alcohol

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

Rupatadine should not be taken with alcohol. Caution should be taken when co-administered.

Pregnancy and breast-feeding

Do not take rupatadine if you are pregnant or breast-feeding.

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking RAZTROL.

Driving and using machines

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

RAZTROL contains lactose. If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor or pharmacist before taking RAZTROL.

3. How to take RAZTROL

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

Always take RAZTROL 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.

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

The usual dose is one tablet of RAZTROL TABLETS once daily with or without food.

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

If you take more RAZTROL 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 RAZTROL

If you forget to take RAZTROL, take it as soon as you remember. Then take your next dose at its usual time. However, if it is almost time for your next dose, skip the dose you missed.

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

If you stop taking RAZTROL

Do not stop taking your medicine without consulting your doctor.

4. Possible side effects

RAZTROL can have side effects.

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

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

- Allergic reactions including sudden life-threatening allergic reaction, symptoms include rash, itching, hives and swelling of the face, lips, tongue or other parts of the body, shortness of breath, wheezing or trouble breathing (anaphylaxis and angioedema).

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

- Palpitations;
- Increased heart rate.

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

Tell your doctor if you notice any of the following:

Frequent side effects:

- Sleepiness;
- Headache;
- Dizziness;
- Dry mouth;
- Unusual weakness;
- Tiredness.

Less frequent side effects:

- Sore throat and discomfort when swallowing;
- Runny or blocked nose, sneezing, facial pressure or pain;
- Increased appetite;
- Irritability;
- Difficulty in concentrating;
- Nosebleed;
- Nasal dryness;
- Redness of the skin and genitals
- Redness of the eye(s), swollen eyelid
- Blisters
- Disorientation
- Walking abnormality
- Increased sweating

- Shaking or tremors
- Cough
- Dry throat
- Difficulty or pain with swallowing
- Nose, throat problems (upper respiratory disorders)
- Nausea (feeling sick),
- Abdominal pain,
- Diarrhoea (loose stools),
- Indigestion,
- Vomiting (being sick),
- Constipation;
- Rash;
- Back pain,
- Joint pain,
- Muscle pain;
- Thirst;
- Generally feeling unwell,
- Fever;
- Abnormal liver function tests (blood creatine phosphokinase, alanine aminotransferase, aspartate aminotransferase etc.)
- Increased weight.

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. You can also report side effects to SAHPRA via the Med Safety APP (Medsafety X SAHPRA) and eReporting platform (whoumc.org) found on SAHPRA website. Suspected adverse reactions can also be reported directly to the HCR via email: pharmacovigilance.africasme@sunpharma.com or tel: +27(0) 12 643 2000. By reporting side effects, you can help provide more information on the safety of RAZTROL.

5. How to store RAZTROL

- Store all medicines out of reach of children.
- Do not use this medicine after the expiry date which is stated on the carton and blister. The expiry date refers to the last day of that month.
- Store at or below 30 ºC.
- Keep the blisters in the outer carton in order to protect from light.
- Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What RAZTROL contains

The active substance is rupatadine.

Each tablet contains 10 mg of rupatadine (as fumarate).

The other ingredients are:

Iron oxide red, iron oxide yellow, lactose monohydrate, magnesium stearate, microcrystalline cellulose, pre-gelatinised starch, purified water.

What RAZTROL looks like and contents of the pack

RAZTROL is a salmon coloured, 6,35 mm ± 0.1 mm round, biconvex, uncoated tablets, plain on both sides.

10 tablets are packed in blister packs consisting of PVC/PVDC foil as a forming material and pre-printed aluminium foil as a lidding material. Each blister will contain 10 tablets. Three such blisters will be packed in a pre-printed carton.

Holder of Certificate of Registration

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