

Package Leaflet: Information for the user

Rupatadine 10mg tablets

rupatadine

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, please ask your doctor or your pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

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

1. What Rupatadine 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 Rupatadine

Do not take Rupatadine

- If you are allergic to rupertadine or any of the other ingredients of this medicine (listed in section 6).

Warnings and precautions

Talk to your doctor or pharmacist before taking Rupatadine.

If you suffer from kidney or liver insufficiency, ask your doctor for advice. The use of Rupatadine 10mg

tablets 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 doctor for advice.

If you are older than 65, ask your doctor or your pharmacist.

Children

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

Other medicines and Rupatadine

Tell your doctor or pharmacist if you are using, have recently used or might use any other medicines.

If you are taking Rupatadine do not take medicines containing ketoconazole (drug for fungal infections) or erythromycin (drug for bacterial infections).

If you are taking central nervous system depressant medicines, statin medicines (medicines used to treat high cholesterol levels) or midazolam (drug used for sedation of short duration), ask your doctor for advice before taking Rupatadine.

Rupatadine 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, at the recommended dose (10mg), does not increase the drowsiness produced by alcohol.

Pregnancy and 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 this medicine.

Driving and using machines

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

Rupatadine contains lactose

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

3. How to take Rupatadine

Always take this medicine exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure. Rupatadine is for adolescents (from 12 years and older) and adults. The usual dose is one tablet (10mg of rupatadine) once daily with or without food. Swallow the tablet with a sufficient quantity of liquid (e.g. one glass of water).

Your doctor will tell you how long your treatment with Rupatadine will last.

If you take more Rupatadine than you should

If you have accidentally taken a high dose of your medicine, talk to your doctor or pharmacist immediately.

If you forget to take Rupatadine

Take your dose as soon as possible and then continue with your tablets at the usual times. Do not take a double dose to make up for forgotten individual doses.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

Common side effects (may affect up to 1 in 10 people):

Sleepiness, headache, dizziness, dry mouth, sensation of weakness and fatigue.

Uncommon side effects (may affect up to 1 in 100 people):

Increased appetite, irritability, difficulty concentrating, nosebleed, nasal dryness, sore throat, cough, dry throat, rhinitis, nausea, abdominal pain, diarrhoea, indigestion, vomiting, constipation, rash, back pain, joint pain, muscle pain, thirst, general discomfort, fever, abnormal liver function test and increased weight.

Rare side effects (may affect up to 1 in 1,000 people):

Palpitations, increased heart rate, and allergic reactions (itching, hives and swelling of the face, lips, tongue or throat).

Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme (website: www.mhra.gov.uk/yellowcard or search for MHRA

Yellow Card in the Google Play or Apple App Store). By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Rupatadine

Keep this medicine out of the sight and 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.

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 Rupatadine contains

- The active substance is rupatadine. Each tablet contains 10mg of rupatadine (as fumarate).
- The other ingredients are pregelatinised maize starch, microcrystalline cellulose, red iron oxide (E-172), yellow iron oxide (E-172), lactose monohydrate and magnesium stearate. See section 2 “Rupatadine contains lactose”.

What Rupatadine looks like and contents of the pack

Rupatadine tablets are round, light salmon coloured and packed in unit blister doses of 3, 7, 10, 15, 20, 30, 50 and 100 tablets. Not all pack sizes may be marketed.

Marketing Authorisation Holder:

Aspire Pharma Limited
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Bedford Road, Petersfield
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Manufacturer:

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