

Package Leaflet: Information for the user

Rupatadine 1mg/ml oral solution

Rupatadine

Read all of this leaflet carefully before you start taking this medicine.

- Keep this leaflet. You may need to read it again.
- If you have further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist (see section 4).

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1. What Rupatadine is and what it is used for

Rupatadine contains the active substance rupatadine which is an antihistamine.

Rupatadine oral solution relieves the symptoms of allergic rhinitis such as sneezing, runny nose, nasal congestion, itching in the eyes and nose in children aged 2 to 11 years.

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) in children aged 2 to 11 years.

2. Before you take Rupatadine

Do not take Rupatadine

- If you are allergic (hypersensitive) to rupatadine or any of the other ingredients of Rupatadine.

Take special care with Rupatadine

If you suffer from kidney or liver insufficiency, ask your doctor for advice. The use of Rupatadine 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 QTc interval on the ECG) which can occur in some forms of heart disease, ask your doctor for advice.

This medicine is not for use in children under 2 years of age or weighing less than 10kg.

Using other medicines

Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription.

If you are taking Rupatadine do not take medicines containing ketoconazole or erythromycin.

If you are taking central nervous system depressant medicines or statin medicines, ask your doctor for advice before taking Rupatadine.

Taking Rupatadine with food and drink

Rupatadine may be taken with or without food.

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

Rupatadine, at dose of 10mg, does not increase the drowsiness produced by alcohol.

Pregnancy and breastfeeding

Do not take Rupatadine during pregnancy and breastfeeding, unless clearly indicated by your doctor.

Ask your doctor or pharmacist for advice before taking any 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.

Important information about some of the ingredients of Rupatadine

This medicinal product contains sucrose, so it may be harmful to the teeth. If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.

This medicinal product contains methyl parahydroxybenzoate, may cause allergic reactions (possibly delayed).

3. How to take Rupatadine

Always take Rupatadine exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure.

Rupatadine oral solution is for oral use.

Dosage in children weighing 25kg or more: 5ml (5mg of rupatadine) of oral solution once a day, with or without food.

Dosage in children weighing equal or more than 10kg to less than 25kg: 2.5ml (2.5mg of rupatadine) of oral solution once a day, with or without food.

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

Instructions for use:

- To open the bottle press the cap and turn it anticlockwise.
- Take the syringe and put it in the perforated stopper and turn the bottle upside down.
- Fill the syringe with the prescribed dose.
- Administer directly from the dosing syringe.
- Wash the syringe after use.

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

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

4. Possible side effects

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

Common side effects (may affect up to 1 in 10 people) are headache and sleepiness.

Uncommon side effects (may affect up to 1 in 100 people) are influenza, nasopharyngitis, upper respiratory tract infection, eosinophilia, neutropenia, dizziness, nausea, eczema, night sweats and fatigue.

If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

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

This medicinal product does not require any special storage conditions.

Keep out of the reach and sight of children.

Do not use Rupatadine after the expiry date which is stated on the bottle and box after EXP. The expiry date refers to the last day of that month. The shelf life after first opening is the same as the expiry date placed on the box and the bottle.

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

6. Further information

What Rupatadine contains

- The active substance is rupatadine. Each ml contains 1mg of rupatadine (as fumarate).
- The other ingredients are propylene glycol, citric acid anhydrous, disodium phosphate anhydrous, saccharin sodium, sucrose, methyl parahydroxybenzoate (E218), quinoline yellow (E104), banana flavour, purified water.

What Rupatadine looks like and contents of the pack

Rupatadine is a clear yellow oral solution.

Rupatadine is packaged in an amber plastic bottle with a perforated stopper and a child-resistant cap. Each bottle contains 120ml Rupatadine solution. A 5ml oral syringe graduated at 0.25ml intervals is provided in the pack.

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