

## Package Leaflet: Information for the user

# Rupatadine 1mg/ml oral solution

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, ask your doctor or 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

This medicine contains the active substance rupertadine which is an antihistamine.

Rupertadine 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.

Rupertadine oral solution 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. 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 in 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 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.

### Children

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

### Other medicines and Rupatadine

Tell your doctor or pharmacist if you are taking, have recently taken or might take 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.

### Rupertadine with food, drink and alcohol

Rupertadine may be taken with or without food.

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

Rupertadine, at a dose of 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, Rupertadine is not expected to influence your ability to drive or use machinery.

However, when you first start taking Rupertadine you should take care to see how the treatment affects you before driving or using machines.

### Rupertadine contains sucrose, methyl parahydroxybenzoate and propylene glycol

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, which may cause allergic reactions (possibly delayed).

This medicine contains 200mg propylene glycol in each ml.

If your child is less than 5 years old, talk to your doctor or pharmacist before giving them this medicine, in particular if they use other medicines that contain propylene glycol or alcohol.

If you are pregnant or breast-feeding, do not take this medicine unless recommended by your doctor. Your doctor may carry out extra checks while you are taking this medicine.

If you suffer from a liver or kidney disease, do not take this medicine unless recommended by your doctor. Your doctor may carry out extra checks while you are taking this medicine.

This medicine contains less than 1mmol sodium (23mg) per 1ml, that is to say essentially 'sodium free'.

### 3. How to take Rupatadine

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

This medicine 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):

Headache and sleepiness.

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

Influenza, nasopharyngitis, upper respiratory tract infection, eosinophilia, neutropenia, dizziness, nausea, eczema, night sweats and fatigue.

#### 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](http://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. This medicinal product does not require any special storage conditions.

Do not use this medicine 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.

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 ml contains 1mg of rupatadine (as fumarate).
- The other ingredients are: propylene glycol (E1520), citric acid anhydrous, disodium phosphate anhydrous, saccharin sodium, sucrose, methyl parahydroxybenzoate (E218), quinoline yellow (E104), banana flavour, purified water. See section 2 "Rupatadine contains sucrose, methyl parahydroxybenzoate and propylene glycol".

#### 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.

#### Marketing Authorisation Holder:

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