PACKAGE LEAFLET: INFORMATION FOR THE USER

Rupafin 1 mg/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 sins 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 Rupafin is and what it is used for

Rupafin contains the active substance rupatadine which is an antihistamine.

Rupafin 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.

Rupafin 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 Rupafin

Do not take Rupafin
- If you are allergic to rupatadine or any of the other ingredients of this medicine (listed in section 6).

Warnings and precautions

Talk to your doctor or pharmacist before taking Rupafin

If you suffer from kidney or liver insufficiency, ask your doctor for advice. The use of Rupafin 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 heart beat (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 10 kg.

Other medicines and Rupafin

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

If you are taking Rupafin 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 Rupafin.

Rupafin with food, drink and alcohol
Rupafin may be taken with or without food.
Rupafin should not be taken in combination with grapefruit juice, as this may increase the level of Rupafin in your body.
Rupafin, at dose of 10 mg, does not increase the drowsiness produced by alcohol.

Pregnancy and breastfeeding
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, Rupafin is not expected to influence your ability to drive or use machinery. However, when you first start taking Rupafin you should take care to see how the treatment affects you before driving or using machines.

Rupafin 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, may cause allergic reactions (possibly delayed).

This medicine contains 200 mg 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 1 mmol sodium (23 mg) per 1 ml, that is to say essentially 'sodium free'.

3. How to take Rupafin

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

Rupafin oral solution is for oral use.

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

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

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

Instructions of 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 Rupafin 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 Rupafin
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) is 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.

Reporting of side effects
If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via HPRA Pharmacovigilance, Earlsfort Terrace, IRL - Dublin 2; Tel: +353 1 6764971; Fax: +353 1 6762517. Website: www.hpra.ie; E-mail: medsafety@hpra.ie. . By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Rupafin

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 to protect the environment.

6. Contents of the pack and other information

What Rupafin contains
- The active substance is rupatadine. Each ml contains 1 mg of rupatadine (as fumarate).
- The other ingredients are propylene glycol (E-1520), citric acid anhydrous, disodium phosphate anhydrous, saccharin sodium, sucrose, methyl parahydroxybenzoate (E-218), quinoline yellow (E-104), banana flavour, purified water. See section 2 “Rupafin contains sucrose, methyl parahydroxybenzoate and propylene glycol”

What Rupafin looks like and contents of the pack
Rupafinis a clear yellow oral solution.
Rupafin is packaged in an amber plastic bottle with a perforated stopper and a child-resistant cap. Each bottle contains 120 ml Rupafin solution. A 5 ml oral syringe graduated at 0.25 ml intervals is provided in the pack.

Marketing Authorisation Holder:
J. Uriach y Compañia, S.A.
Av. Camí Reial, 51-57
E-08184 Palau-solità i Plegamans (Barcelona - Spain)

Manufacturer:
Italfarmaco S.A.
San Rafael, 3
Pol. Ind. Alcobendas
E-28108 Alcobendas (Spain)

Or

Recipharm Parets S.L.
Ramón y Cajal, 2
08150 Parets del Vallés (Spain)

This medicinal product is authorised in the Member States of the EEA under the following names:

Rupatall 1mg/ml oral solution	Belgium, Luxembourg
Rinialer 1mg/ml oral solution	Portugal, Malta
Rupafin 1mg/ml oral solution	Austria, Bulgaria, Croatia, Cyprus, Denmark, Estonia, Germany, Greece, Iceland, Italy, Ireland, Latvia, Liechtenstein, Lithuania, Netherlands, Norway, Poland, Slovenia, Slovak Republic, Spain
Rupatadine 1 mg/ml oral solution	United Kingdom
Wystamm 1mg/mloral solution	France
Tamalis 1mg/mloral solution	Hungary, Czech Republic, Romania
Pafinur 1 mg/ml oral solution	Finland, Sweden

This leaflet was last revised in August 2020