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.
- 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 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. BEFORE YOU TAKE RUPAFIN

Do not take Rupafin
- If you are allergic (hypersensitive) to rupatadine or any of the other ingredients of Rupafin.

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

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 Rupafin 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 Rupafin.

Taking Rupafin with food and drink
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
Do not take Rupafin 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, 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.

Important information about some of the ingredients of Rupafin
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 RUPAFIN

Always take Rupafin exactly as your doctor has told you. You should 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, Rupafin 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.

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 orpharmacist.This includes any possible side effects not listed in this leaflet.You can also report side effects directly via the national reporting system listed in Appendix V*. By reporting side effects you can help provide more information on the safety of this medicine.

5. HOW TO STORE RUPAFIN

This medicinal product does not require any special storage conditions.

Keep out of the reach and sight of children.

Do not use Rupafin 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 Rupafin contains
- The active substance is rupatadine. Each ml contains 1 mg of rupatadine (as fumarate).
- The other ingredients are propylene glycol, citric acid anhydrous, disodium phosphate anhydrous, saccharin sodium, sucrose, methyl parahydroxybenzoate (E-218), quinoline yellow (E-104), banana flavour, purified water.

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 Compañía, 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, 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 approved in