PATIENT PACKAGE INSERT IN ACCORDANCE WITH THE PHARMACISTS' REGULATIONS (PREPARATIONS) - 1986

The medicine is dispensed with a doctor's prescription only

Rupafin oral solution 1 mg/ml

The active ingredient and its quantity:
Each ml of solution contains:
1 mg of rupatadine (as fumarate).

- Inactive ingredients and allergenic in the medicine: see section 6 in the leaflet. See also section 2 "Special warnings regarding use of the medicine".

Read this leaflet carefully in its entirety before using the medicine. This leaflet contains concise information about the medicine. If you have further questions, refer to the doctor or pharmacist.
This medicine has been prescribed for you. Do not pass it on to others. It may harm them even if it seems to you that their ailment/medical condition is similar.

1. WHAT IS THE MEDICINE INTENDED FOR?

Rupafin oral solution 1 mg/ml is indicated for the symptomatic treatment of:

- Allergic rhinitis (including persistent allergic rhinitis) in children aged 2 to 11 years.
- Urticaria in children aged 2 to 11 years.

Therapeutic group: a second-generation antihistamine.

2. BEFORE USING THE MEDICINE

Do not use the medicine if:

- You or your child are sensitive (allergic) to the active ingredient (rupatadine) or to any of the other ingredients of the medicine (see section 6 in this leaflet).

Special warnings regarding use of the medicine
Before using the medicine, inform the doctor if:

- you or your child are suffering 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.
- you or your child have low blood levels of potassium and/or if you or your child have a certain abnormal heart beat pattern (such as prolongation of the QTc interval on the ECG, proarrhythmic conditions such as bradycardia, acute myocardial ischemia) which can occur in some forms of heart disease, ask your doctor for advice.

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

Drug interactions:
If you or your child are taking, or have recently taken, other medicines, including non-prescription medicines and nutritional supplements, inform the doctor or pharmacist.
It is particularly important to inform the doctor or pharmacist if you or your child are taking:

- Medicines that contain itraconazole, ketoconazole, voriconazole, posaconazole, fluconazole (medicines to treat fungal infections), clarithromycin, erythromycin (drugs to treat bacterial infections), HIV protease inhibitors, nefazodone (medicine to treat depression), diltiazem (medicine to treat hypertension and angina pectoris) - Do not take these medicines during the treatment with Rupafin.
- Ciclosporin, tacrolimus, sirolimus, everolimus (immunosuppressive medicines), cisapride;
- Central nervous system depressant medicines, statin medicines such as simvastatin (medicine to treat hypercholesterolemia) or midazolam (drug used for sedation of short duration);

Ask your doctor for advice before taking Rupafin.

Use of the medicine and food:
This medicine may be taken with or without food.
Rupafin should not be taken in combination with grapefruit juice as this may increase the level of the medicine in your body.

Use of the medicine and alcohol:
Rupafin at dose of 10 mg does not increase the drowsiness produced by alcohol.

Pregnancy, breast-feeding and fertility:
Do not take the medicine during pregnancy and breast-feeding, unless clearly indicated by your doctor. Ask your doctor or pharmacist for advice before taking the medicine.

Driving and using machines:
Rupafin 10 mg had no influence on the ability to drive and use machines in a performed clinical trial. Nevertheless, care should be taken before driving or using machinery until your individual reaction to Rupafin has been established.

Important information about some of the ingredients of the medicine:

- This medicinal product contains sucrose, so it may be harmful to the teeth. If you or your child have been diagnosed with 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 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 or your child 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 SHOULD YOU USE THE MEDICINE?

Always use according to the doctor's instructions. Check with your doctor or pharmacist if you are not sure about the dosage and treatment regimen of the medicine.
The dosage and treatment regimen will be determined by the doctor only. The usual dose is:

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

Do not exceed the recommended dose.

Treatment duration - According to the doctor's instructions.

Method of administration - for oral use.

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 or your child have accidentally taken a higher dosage you should contact a doctor or pharmacist immediately.
If you or your child took an overdose, immediately proceed to a doctor or to a hospital emergency room and bring the package of this medicine with you.

If you forgot to take this medicine
If you forget to take the medicine at the scheduled time, do not double the dose.
Take the next dose at the correct time and consult with your doctor.
Adhere to the treatment regimen recommended by the doctor.

Do not take medicines in the dark! Check the label and the dose each time you take the medicine. Wear glasses if you need them.
If you have further questions regarding the use of the medicine, consult a doctor or pharmacist.

4. SIDE EFFECTS

As with any medicine, the use of Rupafin may cause side effects in some users. Do not be alarmed when reading the list of side effects. You may not experience any of 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.

If a side effect occurs, if one of the side effects worsens or if you suffer from a side effect not mentioned in the leaflet, consult your doctor.

Reporting of side effects
Side effects can be reported to the Ministry of Health through link "reporting side effects due to drug treatment" located in the home page of the Ministry of Health website (www.health.gov.il) which refers to online form, or by entering the following link:
https://sideeffects.health.gov.il
Additionally, you may also report to Kamada Ltd by email:
pharmacovigilance@kamada.com

5. HOW SHOULD THE MEDICINE BE STORED?

Avoid poisoning! This medicine and any other medicine must be kept in a safe place out of the reach and sight of children and/or infants to avoid poisoning. Do not induce vomiting without explicit instruction from the doctor.
Do not use after the expiry date (exp. date) that appears on the package and the bottle. The expiry date refers to the last day of that month.

Storage conditions:
Store at room temperature, below 25°C.
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 you no longer use. These measures will help to protect the environment.

6. FURTHER INFORMATION

In addition to the active ingredient, this medicine also contains:
Sucrose, propylene glycol, disodium phosphate anhydrous, citric acid anhydrous, banana flavour, methyl parahydroxybenzoate, saccharin sodium, quinoline yellow (E-104), purified water.

What the medicine looks like and contents of the pack:

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

License holder: Kamada Ltd., Beit Kama

Manufacturer: J. Uriach y Compañia, S.A, Barcelona, Spain

Registration number of the medicine in the National Drug Registry of the Ministry of Health: 166-17-35846

Revised in January 2021 according to MOHs guidelines