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

The medicine is dispensed with a doctor's prescription only

Rupafin Tablets

The active ingredient and its quantity:

Each Tablet contains:

Rupatadine 10 mg (as fumarate)

For the list of Inactive ingredients, see section 6 "Further information". See also section 2 "Special warnings regarding use of the medicine".

Read all of this leaflet carefully before you start taking this 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 only. Do not pass it on to others. It may harm them, even if it seems their medical condition is similar to yours.

1. WHAT IS THE MEDICINE INTENDED FOR?

Rupafin tablets relieves the symptoms of allergic rhinitis and urticaria (an allergic skin rash) in adults and adolescents over 12 years of age.

Therapeutic group: antihistamine second generation.

2. BEFORE USING THE MEDICINE

Do not use the medicine if:

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

Special warnings regarding use of the medicine

Before using the medicine inform the doctor if:

- You suffer from kidney or liver insufficiency, ask your doctor for advice. The use of Rupafin tablets is at present not recommended in patients with impaired kidney or liver functions.
- You have low blood levels of potassium and/or if you have a certain abnormal pattern to your heart beat (known prolongation of the QT interval on the ECG) which can occur in some forms of heart disease, ask your doctor for advice.
- You are older than 65, ask your doctor or your pharmacist.

Children and adolescents

This medicine is not intended for use in children under 12 years of age.

Drug interactions:

If you are taking, or have recently taken, other medicines, including non-prescription medicines and nutritional supplements, inform the doctor or pharmacist. Particularly if you are taking:

- Medicines that contain itraconazole, ketoconazole, voriconazole, posaconazole, fluconazole (medicines to treat fungal infections), clarithromycin, erythromycin (medicines for 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

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

The medicine can be taken with or without food.

Use of the medicine and alcohol

Rupafin, at the recommended dose (10 mg), 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.

There are limited amount of data from the use of the medicine in pregnant and breast-feeding women. As a precautionary measure, it is preferable to avoid the use of the medicine during pregnancy.

Driving and using machines

Rupafin 10 mg had no influence on the ability to drive and use machines. 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

The medicine contains lactose.

If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicine.

3. HOW SHOULD YOU USE THE MEDICINE?

Always take this medicine exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure regarding the dosage and treatment regimen of the medicine.

The dosage and treatment regimen will be determined by the doctor only. The usual dose is one tablet (10 mg of rupatadine) once daily with or without food.

Do not exceed the recommended dose.

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

Method of administration: Swallow the tablet with a sufficient quantity of liquid (e. g. one glass of water).

Rupafin tablets is intended for adults and adolescents (over 12 years of age).

There is no information about splitting, crushing or chewing of the tablet.

If you accidentally took a higher dosage you should refer to your doctor or pharmacist immediately.

If you took an overdose or if a child accidentally swallowed the medicine, refer immediately to a doctor or proceed to a hospital emergency room and bring the medicine package with you.

If you forgot to take this medicine Take your dose as soon as possible and then continue with your tablets at the usual times. Do not take a double dose to make up for forgotten individual doses.

Adhere to the treatment regimen recommended by the doctor.

Even if you are feeling better, do not stop taking this medicine without consulting 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

Like all medicines, Rupafin tablets can cause side effects in some users. Do not be alarmed when reading the list of side effects. You may not experience any of them.

Severe allergic reaction may occur in rare cases. **Stop the use and refer to a doctor immediately if you experience itching, hives or red spots on the skin, swelling of the face, lips, tongue or throat.**

Common side effects (may affect up to 1 in 10 people): sleepiness, headache, dizziness, dry mouth, sensation of weakness and fatigue.

Uncommon side effects (may affect up to 1 in 100 people): increased appetite, irritability, difficulty concentrating, nosebleed, nasal dryness, sore throat, cough, dry throat, rhinitis, pharyngitis, nausea, abdominal pain, diarrhoea, indigestion, vomiting, constipation, rash, back pain, joint pain, muscle pain, thirst, general discomfort, fever, abnormal liver function test and increased weight.

Rare side effects (may affect up to 1 in 1,000 people): palpitations, increased heart rate.

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 this medicine after the expiry date (exp. date) which is stated on the carton and blister. The expiry date refers to the last day of that month.

Store at room temperature, below 25°C.

Keep the blisters in the original carton in order to protect from light.

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. FURTHER INFORMATION

In addition to the active ingredient, this medicine also contains:

Lactose monohydrate, microcrystalline cellulose, pregelatinised maize starch, magnesium stearate, yellow iron oxide (E-172), red iron oxide (E-172).

What the medicine looks like and contents of the pack:

Tablets are round, light pink-salmon coloured, packed in blisters. 30 tablets in a package.

License holder: Kamada Ltd., Beit Kama

Manufacturer: Noucor Health S.A., Barcelona, Spain.

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Registration number of the medicine in the National Drug Registry of the Ministry of Health: 164-90-35494