

## Package Leaflet: Information for the user

# Rupafin® 10mg Tablets

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 further questions, please ask your doctor or your 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 Rupafin is and what it is used for
2. What you need to know before you take Rupafin
3. How to take Rupafin
4. Possible side effects
5. How to store Rupafin
6. Contents of the pack and other information

### 1. What Rupafin is and what it is used for

Rupatadine is an antihistamine.

Rupafin relieves the symptoms of allergic rhinitis such as sneezing, runny nose, itching in the eyes and nose.

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).

### 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 10mg tablets 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 QT interval on the ECG)

which can occur in some forms of heart disease, ask your doctor for advice.

If you are older than 65, ask your doctor or your pharmacist.

#### Children

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

#### Other medicines and Rupafin

Tell your doctor or pharmacist if you are using, have recently used or might use any other medicines.

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.

#### Rupafin with food, drink and alcohol

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

Rupafin, at recommended dose (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, 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 lactose

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

### 3. How to take Rupafin

Always take this medicine exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure. Rupafin is for adolescents (from 12 years and older) and adults. The usual dose is one tablet (10mg of rupatadine) once daily with or without food. Swallow the tablet with a sufficient quantity of liquid (e. g. one glass of water).

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

### **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**

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.

## **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):

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, 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, and allergic reactions (itching, hives and swelling of the face, lips, tongue or throat).

### **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)).

By reporting side effects you can help provide more information on the safety of this medicine.

## **5. How to store Rupafin**

Keep out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the carton and blister. The expiry date refers to the last day of that month.

Keep the blisters in the outer 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 protect the environment.

## **6. Contents of the pack and other information**

### **What Rupafin contains**

- The active substance is rupatadine. Each tablet contains 10mg of rupatadine (as fumarate).
- The other ingredients are pregelatinised maize starch, microcrystalline cellulose, red iron oxide (E-172), yellow iron oxide (E-172), lactose monohydrate and magnesium stearate.

### **What Rupafin looks like and contents of the pack**

Rupafin are round, light salmon coloured tablets packed in unit blister doses of 3, 7, 10, 15, 20, 30 50 and 100 tablets. Not all pack sizes may be marketed.

### **Marketing Authorisation Holder and Manufacturer:**

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