

## Package Leaflet: Information for the user

### **Rupafin 10 mg 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 any 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 10 mg 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 QTc 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 (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 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 (10 mg 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) are sleepiness, headache, dizziness, dry mouth, sensation of weakness and fatigue. Uncommon side effects (may affect up to 1 in 100 people) are increased appetite, irritability, difficulty concentration, 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) are 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, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via HPRC Pharmacovigilance, Earlsfort Terrace, IRL - Dublin 2; Tel: +353 1 6764971; Fax: +353 1 6762517. Website: [www.hpra.ie](http://www.hpra.ie); E-mail: [medsafety@hpra.ie](mailto: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.

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 to protect the environment.

## 6. Contents of the pack and other information

### What Rupafin contains

- The active substance is rupatadine. Each tablet contains 10 mg 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

NOUCOR HEALTH, S.A.

Av. Camí Reial, 51-57

E-08184 Palau-solità i Plegamans (Barcelona - Spain)

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

**Rupatall 10 mg Tablets**

**Rinialer 10 mg Tablets**

**Rupafin 10 mg Tablets**

**Wystamm 10 mg Tablets**

**Tamalis 10 mg Tablets**

**Pafinur 10 mg Tablets**

**Belgium, Luxembourg,**

**Portugal, Malta**

**Austria, Bulgaria, Croatia, Cyprus, Denmark, Estonia,  
Germany, Greece, Iceland, Italy, Ireland, Latvia,  
Liechtenstein, Lithuania, Netherlands, Norway, Poland,  
Slovenia, Slovak Republic, Spain, United Kingdom**

**France**

**Hungary, Czech Republic, Romania**

**Finland, Sweden**

**This leaflet was last revised in**