

PATIENT INFORMATION LEAFLET

SCHEDULING STATUS:

S2

RUPAXINE10 mg Tablets

Rupatadine fumarate

Contains sugar: Lactose monohydrate 38.00 mg

Read all of this leaflet carefully because it contains important information for you.

RUPAXINE is available without a doctor's prescription, for you to treat a mild illness. Nevertheless, you still need to use RUPAXINE carefully to get the best results from it.

- Keep this leaflet. You may need to read it again.
- Do not share RUPAXINE with any other person.
- Ask your health care provider or pharmacist if you need more information or advice.
- You must see a doctor if your symptoms worsen or do not improve.

What is in this leaflet

1. What RUPAXINE is and what it is used for
2. What you need to know before you take RUPAXINE
3. How to take RUPAXINE
4. Possible side effects
5. How to store RUPAXINE
6. Contents of the pack and other information

1. WHAT RUPAXINE IS AND WHAT IT IS USED FOR

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

RUPAXINE 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 USE RUPAXINE

Do not use RUPAXINE

- If you are hypersensitive (allergic) to rupatadine and/or any of the other ingredients of RUPAXINE.
- RUPAXINE is not recommended for use in children below 12 years of age.
- If you are pregnant and breastfeeding

Warnings and precautions

Special care should be taken with RUPAXINE

- If you have or have had liver or kidney disease, ask your doctor for advice. The use of RUPAXINE is not recommended in patients with impaired kidney or liver functions.

RUPAXINE:

- Should be used with caution in patients with known prolongation or longer period of the QT Interval (abnormal heartbeat) which means the time between the Q wave and the end of the T wave in the heart's electrical cycle.
- Patients with uncorrected low potassium.
- Patients with ongoing polydysrhythmic conditions which means it is a medicine caused or medicine aggravated heart rhythm condition, such as clinically significant slow heart rate.
- And acute decreased blood flow to your heart,
- If you are older than 65, ask your doctor or pharmacist before taking RUPAXINE.

Children:

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

Other medicines and RUPAXINE:

Always tell your health care provider if you are taking any other medicine. (This includes all complementary and traditional medicines).

If you are taking RUPAXINE do not take the following medicines:

- ketoconazole, itraconazole, voriconazole, posaconazole, fluconazole (medicine for fungal infections),
- Erythromycin, clarithromycin (drug medicine for bacterial infections),
- Diltiazem (used for high blood pressure),
- Nefazodone (used to treat depression),
- Atazanavir, darunavir (used to treat HIV infection),
- Statins such as simvastatin, lovastatin (medicines used to treat high cholesterol levels).

RUPAXINE with food, drink and alcohol

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

RUPAXINE should be used with caution when administered with alcohol.

Pregnancy, breastfeeding and fertility:

If you are pregnant or breastfeeding your baby, think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist or other healthcare professional for advice before taking this medicine.

The use of RUPAXINE is contraindicated during pregnancy.

As rupatadine is excreted in animal milk and due to potential harmful effects in neonates, the use of RUPAXINE is contraindicated during breastfeeding.

Driving and using machinery

At the recommended dosage, RUPAXINE is not expected to influence your ability to drive or use machinery. However, when you first start taking RUPAXINE you should take care to see how the treatment affects you before driving or using machines.

RUPAXINE contains lactose monohydrate

RUPAXINE contains lactose. Patients with the rare hereditary conditions of lactose or galactose intolerance should not take RUPAXINE.

3. HOW TO USE RUPAXINE

Always use RUPAXINE exactly as described in this leaflet or as your doctor or pharmacist have told you. Check with your doctor or pharmacist if you are not sure.

The recommended dosage for adults and adolescents (over 12 years of age) is 10 mg (one tablet) once a day 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 RUPAXINE will last.

If you use more RUPAXINE than you should

In the event of overdosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison centre.

If you forget to use RUPAXINE

Do not use a double dose to make up for forgotten individual doses.

4. Possible side effects

RUPAXINE can have side effects.

Not all side effects reported for RUPAXINE are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking RUPAXINE, please consult your doctor, pharmacist or other healthcare professional for advice.

If any of the following happens, stop taking RUPAXINE and tell your doctor immediately or go to the casualty department at your nearest hospital:

- Allergic reactions including sudden life-threatening allergic reaction, symptoms include rash, itching, hives and swelling of the face, lips, tongue or other parts of the body, shortness of breath, wheezing or trouble breathing (anaphylaxis and angioedema).

These are all very serious side effects. If you have them, you may have had a serious reaction to RUPAXINE. You may need urgent medical attention or hospitalisation.

Tell your doctor immediately or go to the casualty department at your nearest hospital if you notice any of the following:

- Changes in the way your heart beats – rapid or irregular.

These are all serious side effects. You may need urgent medical attention.

Tell your doctor if you notice any of the following:

Frequent side effects:

- Dizziness,
- Headache,
- Sleepiness,
- Dry mouth,
- Weakness such as lack of energy and strength,
- Feeling tired.

Less Frequent side effects:

- Sore throat,
- Stuffy and runny nose,
- Increased appetite,
- Irritability,
- Disturbance in attention
- Rapid and irregular heartbeat,
- Cough,
- Dry throat,
- Nose bleeding,
- Nasal dryness,
- Stomach pain,
- Diarrhoea (loose stools),
- Indigestion,
- Nausea,
- Vomiting,
- Constipation,
- Rash,
- Joint pain,
- Back pain,
- Muscle pain,
- Feeling generally unwell,
- Fever,
- Thirst,
- Abnormal liver function tests (alanine aminotransferase, aspartate aminotransferase, blood creatine phosphokinase etc.)
- Weight increase.

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

Reporting of side effects

If you get side effects, talk to your doctor or pharmacist. You can also report side effects to SAHPRA via the Med Safety APP (Medsafety X SAHPRA) and eReporting platform (who-umc.org) found on SAHPRA website.

By reporting side effects, you can help provide more information on the safety of RUPAXINE.

May also report to Adcock Ingram Limited using the following email: Adcock.AEReports@adcock.com

5. HOW TO STORE RUPAXINE

Store all medicines out of reach of children.

Store at or below 25 °C.

Keep blisters in outer carton until required for use.

KEEP OUT OF CHILDREN

Do not use after the expiry date stated on the label / carton / bottle

Return all unused medicine to your pharmacist.

6. CONTENTS OF THE PACK AND OTHER INFORMATION

What RUPAXINE contains:

RUPAXINE contains the active substance rupatadine. Each tablet contains 10 mg of rupatadine (as rupatadine fumarate).

The other ingredients are lactose monohydrate, magnesium stearate, microcrystalline cellulose PH 102, pregelatinized starch (Maize), red iron oxide E172, yellow iron oxide E172

RUPAXINE contains sugar

What RUPAXINE looks like and contents of the pack:

RUPAXINE tablets are round, light-salmon coloured.

RUPAXINE is contained in thermoformed blisters made of silver Aluminum (25 µm) and PVC (250 µm)/PVdC clear film (40 g/m²).

Pack sizes: 1x10, 2x10 and 3x10 blisters.

Not all pack sizes will be marketed.

Holder of Certificate of Registration

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Access to the corresponding professional information

It is contained in the packaging of the medicine