

Rulid® 150 mg

roxithromycine

coated tablets

sanofi aventis

Read all of this leaflet carefully before you start taking this medicine.

- Keep this leaflet. You may need to read it again.
- If you have any further questions or if you are unsure of anything, ask your doctor or pharmacist for more information.
- This medicine has been prescribed for you personally and you should not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- If any of the side effects becomes serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

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1. WHAT Rulid 150 mg coated tablets ARE AND WHAT THEY ARE USED FOR

This medicine is used to treat certain bacterial infections susceptible to this drug.

2. BEFORE YOU TAKE Rulid 150 mg coated tablets

If your doctor has informed you that you have an intolerance to certain sugars, contact him/her before taking this medicine.

DO NOT TAKE this medicine in the following situations:

- allergy to antibiotics of the macrolide class,
- in combination with:
 - ergotamine and dihydroergotamine (medicines used to treat migraines),
 - cisapride (medicine used to treat reflux),(see Taking/using other medicines)
- women breast-feeding a child receiving treatment with cisapride (see Pregnancy and breast-feeding).

Take special care with Rulid 150 mg coated tablets

Special warnings

As this medicine contains glucose, you should not take it if you have glucose-galactose malabsorption syndrome.

Inform your doctor if you have liver failure. Taking this medicine at the same time as colchicine or dopaminergic ergot alkaloids (bromocriptine, cabergoline, lisuride, pergolide) should be avoided. (See Taking/using other medicines).

Precautions for use

It is important that you inform your doctor if you have liver disease, as your treatment will need to be adjusted.

Inform your doctor if you are pregnant or breast-feeding.

IF YOU ARE UNSURE OF ANYTHING, DO NOT HESITATE TO ASK YOUR DOCTOR OR PHARMACIST FOR ADVICE.

Inform your doctor of any change in cardiac activity detected by an ECG, hypokalemia (abnormally low blood potassium levels),

uncorrected hypomagnesemia (abnormally low blood magnesium levels), bradycardia (slow heart rhythm) or if you are taking medication to eliminate abnormal heart rhythms.

Inform your doctor if you have a neuromuscular disorder as this medicine may make it worse.

To avoid possible interactions between several medicines, you must always inform your doctor or pharmacist of any other treatment you may be taking.

Keep out of the reach and sight of children.

Taking/using other medicines

This medicine MUST NOT BE TAKEN in combination with ergotamine and dihydroergotamine (medicines used to treat migraines) or cisapride (medicine used to treat reflux) (see DO NOT TAKE this medicine in the following situations).

This medicine MUST BE AVOIDED in combination with colchicine or dopaminergic ergot alkaloids (bromocriptine, cabergoline, lisuride, pergolide) (See Special warnings).

Inform your doctor or pharmacist if you are taking or have recently taken any other medicines, including those obtained without a prescription.

Pregnancy and breast-feeding

Pregnancy

This medicine should preferably not be used during pregnancy.

If you discover that you are pregnant during treatment, consult your doctor who is the only person who can assess whether treatment should be continued.

Breast-feeding

You may breast-feed during treatment with this medicine. However, if your child develops digestive disorders (candidiasis, diarrhea), stop breast-feeding and consult your doctor without delay.

If your breast-fed child is being treated with cisapride, use of this medicine is contraindicated.

AS A GENERAL RULE, DURING PREGNANCY OR BREAST-FEEDING, YOU SHOULD ALWAYS ASK YOUR DOCTOR OR PHARMACIST FOR ADVICE BEFORE TAKING ANY MEDICINE.

Driving and using machines

The risk of dizziness may make driving or using certain machines dangerous.

List of excipients that must be taken into account for safe use in some patients: glucose

3. HOW TO TAKE Rulid 150 mg coated tablets

How Rulid 150 mg coated tablets should be taken

IN ALL CASES, STRICTLY FOLLOW YOUR DOCTOR'S PRESCRIPTION.

COMPLY WITH THE DURATION OF TREATMENT.

As an indication:

In adults, the usual dosage is one tablet morning and evening, taken preferably before meals.

How long Rulid 150 mg coated tablets should be taken

To be effective, this antibiotic has to be used regularly at the prescribed doses, and for as long as your doctor has recommended it.

If fever and/or any other symptom disappear(s), this does not mean that you have completely recovered.

Possibly feeling tired is not due to the antibiotic treatment, but to the infection itself. Decreasing doses or stopping treatment would have no effect on this feeling and would delay your recovery.

Specific case: the treatment duration for certain cases of sore throat is 10 days.

4. POSSIBLE SIDE EFFECTS

Like all medicines, Rulid 150 mg coated tablets can cause side effects, although not everybody gets them:

- digestive effects: nausea, vomiting, stomach pain, diarrhea,
- cardiac effects: ventricular rhythm disturbances, cardiac arrest,
- neurological effects: dizziness, headache, abnormal sensations in the fingertips, taste and smell disturbances,
- liver effects: transient increase in certain liver enzymes (transaminases) which may result in cholestatic hepatitis (a type of non-viral hepatitis) or jaundice,
- severe allergic reactions: angioedema (type of hives with sudden swelling of the face and neck), difficulty breathing,
- skin eruptions, hives, skin reactions with blisters, purpura (small red or bluish spots on the skin),
- psychiatric effects: hallucination.

If you notice any side effects not listed in this leaflet or if any of the side effects become serious, please tell your doctor or pharmacist.

5. HOW TO STORE Rulid 150 mg coated tablets

Keep out of the reach and sight of children. Do not use Rulid 150 mg coated tablets after the expiry date indicated on the box. Store this medicine at a temperature no higher than 25°C.

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

6. FURTHER INFORMATION

What Rulid 150 mg coated tablets contain

The active substance is:

Roxithromycine150 mg
For one coated tablet.

The other ingredients are:

Hydroxypropylcellulose, polyoxyethylene-polyoxypropylene glycol (Pluronic® F68), povidone, anhydrous colloidal silica (Aerosil® 200), magnesium stearate, talc, maize starch.

Coating: methylhydroxypropylcellulose (6 cps), anhydrous glucose, titanium dioxide (E171), propylene glycol.

What Rulid 150 mg coated tablets are and contents of the outer packaging

Coated tablets. Box of 10 tablets.

Not all pack sizes may be marketed.

Marketing Authorization Holder and Operating Company

sanofi-aventis France

1-13, Boulevard Romain Rolland
75014 Paris

France

Manufacturer

SANOI WINTHROP INDUSTRIE
56, Route de Choisy au Bac
60205 Compiègne
France

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RECOMMENDATIONS/HEALTH EDUCATION

What you should know about antibiotics

Antibiotics are effective in fighting infections caused by bacteria. They are not effective against those caused by viruses.

Your doctor has therefore chosen to prescribe this antibiotic for you because it is suitable for you and for the disease you have.

Bacteria are able to survive or to reproduce despite the effect of an antibiotic. This is known as resistance and makes some antibiotic treatments ineffective.

Inappropriate or excessive use of antibiotics increases resistance.

You may promote the growth of resistant bacteria and thus slow down your recovery, or even make this medicinal product ineffective, if you do not comply with the following:

- prescribed dose,
- administration times,
- duration of treatment.

Therefore, to maintain the efficacy of this medicine:

1- Only use an antibiotic when your doctor has prescribed it for you.

2- Comply strictly with your prescription.

3- Do not reuse an antibiotic without a medical prescription even if you think you are fighting an apparently similar disease.

4- Never give your antibiotic to someone else - it may not be appropriate for their disease.

5- Once your treatment is completed, bring all opened boxes to your pharmacist for proper disposal of this medicine.