

Package leaflet: Information for the user

Roxithromycin Orifarm 150 mg and 300 mg film-coated tablets

Roxithromycin

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, ask your doctor, pharmacist or nurse.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

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1. What Roxithromycin Orifarm is and what it is used for
2. What you need to know before you take Roxithromycin Orifarm
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1. What Roxithromycin Orifarm is and what it is used for

Roxithromycin Orifarm is a macrolide antibiotic. Roxithromycin Orifarm prevents bacteria from growing, by interfering with their protein synthesis.

It is used to treat infections caused by roxithromycin-sensitive bacteria like respiratory tract infections, genito-urinary tract infections, soft tissue infections and infections in the skin.

Your doctor may have prescribed other use. Always follow your doctor's instructions.

2. What you need to know before you take Roxithromycin Orifarm

Do not take Roxithromycin Orifarm

- if you are allergic to roxithromycin, to any of the other ingredients of this medicine (listed in section 6) or to other macrolide antibiotic, like erythromycin
- if you are concurrently taking ergotalkaloids (anti-migraine medicine)
- if you are concurrently taking drugs containing terfenadine or astemizole (anti-allergy medicine), cisapride (stomach medicine), or pimozone (anti-psychotic medicine)

Warnings and precautions

Talk to your doctor, pharmacist or nurse before taking Roxithromycin Orifarm:

- if you suffer from hypokalaemia (low plasma potassium concentration)
- if you have a heart disease
- if you have an impaired hepatic function
- if you have diarrhoea
- if you a body weight of less than 40 kg since no documented effect has been shown
- if you have an intolerance to some sugars

Other medicines and Roxithromycin Orifarm

Roxithromycin Orifarm has the potential to interact with other drugs. Talk to your doctor if you are taking or have recently taken any of the following medicines :

- terfenadine or astemizole (anti-allergy medicine)

- cisapride (stomach medicine)
- pimozide (antipsychotic medicine)
- digoxin or other heart glucosid (cardiac medicine)
- disopyramide (medicine treating abnormal heart rhythms)
- ergotamine or dihydroergotamine (anti-migraine medicine)
- midazolam or triazolam (sleeping medicine)
- ciclosporin (used in organ transplantations)
- theophylline (asthma medicine)
- bromocriptine (medicine for Parkinson's disease)
- statin (cholesterol lowering medicine)

Antacids containing both aluminium and magnesium may possibly reduce the efficacy of Roxithromycin Orifarm. Take antacids 2 hours before or after Roxithromycin Orifarm.

Roxithromycin Orifarm may possibly reduce the efficacy of contraceptives.

Please tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines, including medicines obtained without a prescription, natural medicines and strong vitamins and minerals.

Roxithromycin Orifarm with food and drink

Take the Roxithromycin Orifarm on an empty stomach at least 15 minutes before a meal. The tablets should be administered with a sufficient amount of water.

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.

Pregnancy

Do not take Roxithromycin Orifarm while you are pregnant without your doctor's prescription.

Breast-feeding

Do not take Roxithromycin Orifarm while breast-feeding without your doctor's prescription. Roxithromycin (the active ingredient) will be excreted in the breast milk.

Driving and using machines

Caution should be exercised when driving and using machines as Roxithromycin can cause dizziness.

Roxithromycin Orifarm contains glucose

The tablets contain a small amount of glucose.

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 Roxithromycin Orifarm

Always take this medicine exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure.

Take the Roxithromycin Orifarm on an empty stomach at least 15 minutes before a meal. The tablets should be administered with a sufficient amount of water.

Adults and children with a body weight of more than 40 kg: Your doctor will prescribe an individual dose. The usual dose is 150 mg twice a day (every 12 hours) or 300 mg once daily. It is imperative that you continue treatment until the course prescribed by your doctor is completed. Do not stop even if the symptoms disappear before the end of the course.

Impaired liver function:

Roxithromycin Orifarm should be used with caution in cases of liver insufficiency, dosage should be reduced.

Always follow your doctor's instructions. Each individual has different needs. You should not change or stop your treatment without consulting your doctor.

If you take more Roxithromycin Orifarm than you should

If you take more Roxithromycin Orifarm than you should, you can experience nausea, vomiting and diarrhoea. Undesirable effects such as headache and dizziness may appear and become potentiated by overdose.

If you take more Roxithromycin Orifarm than you should, tell a doctor or pharmacist.

If you forget to take Roxithromycin Orifarm

Do not take a double dose to make up for a forgotten tablet.

If you have any further questions on the use of this product, ask your doctor or pharmacist.

If you stop taking Roxithromycin Orifarm

You should not change or stop your treatment without consulting your doctor. It is vital to take the tablets according to your doctor's instructions as regards the duration of treatment.

If you do not follow the treatment for the days fixed, there is a risk that the bacteria will survive and trigger a new infection.

If you have any further questions on the use of this medicine, ask your doctor, pharmacist or nurse.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

Common (may affect up to 1 in 10 people)

- Nausea, stomach ache

Uncommon (may affect up to 1 in 100 people)

- Diarrhoea, indigestion, vomiting, constipation, wind
- Elevated liver-enzyme levels
- Redness, rash, urticaria
- Headache, dizziness

Rare (may affect up to 1 in 1,000 people)

- Changes in blood count
- Transitory deafness, loss of hearing, vertigo, tinnitus
- Asthma-like symptoms
- Impairment of liver and pancreas
- Eczema, rash, Stevens Johnson syndrome (symptoms with fever, rash or infection).
- Weakness, discomfort, oedema, severe allergic response
- Disturbances of taste and/or smell.

On long-term use, secondary infection (supra-infection) with resistant bacteria or fungi is possible.

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 [the national reporting system listed in

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

5. How to store Roxithromycin Orifarm

Keep out of the sight and reach of children.

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

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 Roxithromycin Orifarm contains

- The active substance is roxithromycin. One tablet contains 150 mg or 300 mg roxithromycin.
- The other ingredients are:
Tablet core: Maize starch, hydroxypropyl cellulose, water free colloidal silica, sodium starch glycolate (type A and B), poloxamer 188, povidone (K30), magnesia stearate, and talcum.
Coating : Propylene glycole, water free glucose, hypromellose, and titanium dioxide (E171).

What Roxithromycin Orifarm looks like and contents of the pack

Roxithromycin Orifarm 150 mg; white or almost white, round, convex film-coated tablet. Diameter: 9 mm

Roxithromycin Orifarm 300 mg; white or almost white, round, convex film-coated tablet. Diameter: 11 mm

Pack sizes (blister packs):

150 mg: 14, 15, 20, 100 tablets

300 mg: 7, 10 tablets

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

Orifarm Generics A/S

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

Denmark, Finland: Roxithromycin Orifarm

This leaflet was last revised in 04/2013