

Package leaflet: Information for the user

Roximstad 150 mg film-coated tablets
Roximstad 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 or 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 Roximstad is and what it is used for
2. What you need to know before you take Roximstad
3. How to take Roximstad
4. Possible side effects
5. How to store Roximstad
6. Contents of the pack and other information

1. What Roximstad is and what it is used for

Roximstad film-coated tablets contain the active ingredient roxithromycin. Roxithromycin belongs to a group of medicines known as macrolide antibiotics. These are medicines used to fight infections caused by bacteria.

Roximstad is used to

- treat bacterial infections of the airways including:
 - some types of a serious lung infection (pneumonia) caught in the community (community acquired pneumonia).
- treat urinary tract infections caused by a certain bacterium.
- treat the following diseases in people who cannot take a type of medicine called beta-lactam antibiotics:
 - infection/inflammation of the tonsils (tonsillitis)
 - infection/inflammation of the throat (pharyngitis)
 - sudden middle ear infection (acute otitis media)
 - skin and soft tissue infections caused by bacteria, such as boils (furunculosis), skin infections (pyoderma, impetigo and erysipelas).

2. What you need to know before you take Roximstad

DO NOT take Roximstad

- if you are allergic to roxithromycin or any of the other ingredients of this medicine (listed in section 6)
- if you are allergic (hypersensitive) to other similar antibiotics of the macrolide type
- if you are also taking any of the following medicines:

- cisapride (used to treat acid reflux)
- ergot alkaloid derivatives (such as ergotamine and dihydroergotamine) used to treat migraine
- pimozone (used to treat serious mental disorders)
- astemizole and terfenadine (antihistamines used for hay fever)
- if you were born with a heart condition called long QT syndrome
- if you have a family history of long QT syndrome. Your doctor will check for long QT syndrome using a heart recording called an ECG
- if you have developed a heart condition called QT interval prolongation

Warnings and precautions

Talk to your doctor before taking Roximstad if you have or have had any medical condition, especially the following:

- if you have migraine headaches and are taking ergot alkaloids (such as ergotamine and dihydroergotamine)
- if your heart muscle does not get enough blood (coronary heart disease)
- if you have a history of irregular heart beats (ventricular arrhythmias)
- if you have an imbalance in the salt (electrolyte) or fluid level of your body. This includes:
 - a low level of potassium in the blood (hypokalaemia)
 - a low level of magnesium in the blood (hypomagnesaemia)
- if you have slow heart beat (bradycardia) of less than 50 beats per minute
- if you are taking medicines which can cause a heart condition called long QT syndrome, e.g.:
 - quinidine, procainamide, disopyramide, dofetilide, amiodarone (used to treat heart problems)
 - citalopram, tricyclic antidepressants (used to treat depression/mood disorders)
 - methadone (used to treat drug addiction)
 - antipsychotic medicines (e.g. phenothiazines)
 - medicines used to treat bacterial infections (antibiotics) belonging to a group called fluoroquinolones, e.g. moxifloxacin
- if you have a disease that is treated with medicines called protease inhibitors (e.g. telaprevir)
- if you are taking medicines which are used to treat fungal infections (e.g. ketoconazole, fluconazole, pentamidine)
- If you have a mild-moderate liver disease
- if you have severe liver disease you should normally not take Roximstad. For example, if you have a scarred and fibrous liver (cirrhosis) together with:
 - inflamed liver (hepatitis) or
 - a build-up of fluid in the abdomen (ascites). See also section 3, How to take Roximstad.
 However, your doctor may decide that you must take Roximstad to deal with your infection. In this case, your dose will be decreased.

Your doctor will check your liver function regularly if:

- you have signs of liver disease
 - you have suffered from poor liver function after taking roxithromycin before
- If your liver function gets worse during treatment, your doctor may tell you to stop taking Roximstad.

Pseudomembranous colitis

This is an infection causing inflammation of the large intestine. It can result in severe runny stools (diarrhoea) which can last for days or weeks, and can occur during or after treatment. If you have these symptoms:

- you should stop taking Roximstad immediately and see your doctor
- do not take medicines that slow down the normal passage of food through your system.

Your doctor will prescribe another medicine to treat your symptoms.

Allergic (hypersensitivity) reactions

Some patients have had serious allergic reactions when taking roxithromycin. Reactions include a

serious allergic reaction called anaphylaxis. Symptoms of anaphylaxis may include swelling of the skin, of the face, limbs, tongue or throat, and breathing difficulties. Occasionally these reactions can be life threatening. If you have an allergic reaction:

- stop taking Roximstad
- contact your doctor or go to your nearest hospital immediately

Serious skin reactions

If a widespread, severe skin rash occurs, including skin blistering or peeling, as well as signs of flu and fever (Stevens-Johnson syndrome), a general unwell feeling, fever, chills and muscle aches (toxic epidermal necrolysis), or a red, scaly rash with bumps under the skin and blisters (acute generalised exanthematous pustulosis), refer to a doctor immediately since these skin effects may be life-threatening.

Irregular heartbeat (arrhythmia)

If you develop signs of an irregular or rapid heartbeat during treatment:

- stop taking Roximstad
- see your doctor immediately. He will check your heartbeat by making a recording (ECG)

A disorder causing muscle weakness (myasthenia gravis)

If you suffer from myasthenia gravis your symptoms of myasthenia gravis may get worse. This may affect your breathing muscles and your breathing may get dangerously weak. If your symptoms get worse you should stop taking Roximstad and see your doctor immediately.

Blood and urine testing

If you need to take Roximstad for longer than two weeks your doctor will regularly check:

- your kidney function
- your liver function
- your blood

Children and patients weighing less than 40 kg

Roximstad should not be used by:

- children under 6 years
- patients with a body weight of less than 40 kg

Other medicines and Roximstad

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

DO NOT take Roximstad if you are already taking any of these drugs (see Section 2).

- cisapride (used to treat night-time heartburn)
- ergot alkaloids (such as ergotamine and dihydroergotamine) used to treat migraine headaches
- pimozone (used to treat mental disorders like schizophrenia)
- astemizole and terfenadine (used to treat hay fever)

The effect of your Roximstad medicine can be affected by or can affect the following medicines:

- ciclosporin (used to prevent rejection of organ transplants)
- midazolam (a sedative medicine used for its calming effect and to reduce anxiety)
- anticoagulants (used to thin the blood, e.g. warfarin)
- cardiac glycosides (heart stimulants, e.g. digoxin)
- disopyramide (a heart medicine)
- theophylline (used to treat asthma and lung disease)
- bromocriptine (used to treat Parkinson disease and diseases in which a decrease of a specific hormone (prolactin) is indicated)
- rifabutin (used to treat tuberculosis)

- medicines which can cause a heart condition called long QT syndrome, e.g.:
 - quinidine, procainamide, disopyramide, dofetilide, amiodarone (used to treat heart problems)
 - citalopram, tricyclic antidepressants (used to treat depression/mood disorders)
 - methadone (used to treat drug addiction)
 - antipsychotic medicines (e.g. phenothiazines)
 - medicines used to treat bacterial infections (antibiotics) belonging to a group called fluoroquinolones, e.g. moxifloxacin
- if you have a disease that is treated with medicines called protease inhibitors (e.g. telaprevir)
- if you are taking medicines which are used to treat fungal infections (e.g. ketoconazole, fluconazole, pentamidine)
- simvastatin or other statins (medicines used to lower the cholesterol)

Oral contraceptives: You should note that the oral contraceptive pill may be less effective when you take Roximstad.

Roximstad with food and drink

You should take Roximstad at least 15 minutes before a meal which ensures that your body absorbs the medicine rapidly. Take Roximstad with something to drink, e.g. a glass of water.

Pregnancy and breast-feeding

Ask your doctor or pharmacist for advice before taking any medicine.

Studies in animals have not shown any harmful effects of Roximstad. However, the use of Roximstad in pregnant or breast-feeding women has not been studied.

If you are pregnant, **only use Roximstad if your doctor indicates it is absolutely necessary.**

Breast-feeding

Roxithromycin passes into breast milk. If you are breast-feeding, **only use Roximstad if your doctor indicates it is absolutely necessary.**

Driving and using machines

When taking Roximstad dizziness can occasionally occur. Visual impairment and blurred vision may also have an effect on a patient's ability to drive or operate machinery. If you experience these symptoms you must not drive or use machines.

Roximstad contains milk sugar (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 Roximstad

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

You should take Roximstad tablets at least 15 minutes before a meal with some liquid, e.g. water.

Adults, the elderly, and children weighing at least 40 kg

The recommended dose is 150 mg Roximstad twice a day (every 12 hours).

If you are being treated for pneumonia your doctor may tell you to take 300 mg Roximstad once a day.

If you have kidney or liver problems

If you have impaired kidney function your Roximstad dose will not need to be adjusted.

If you have mild to moderate liver disease your doctor will decide if you must take Roximstad or not.

If you have severe liver disease you should normally not take Roximstad. For example, if you have a scarred or fibrous liver (cirrhosis of the liver together with:

- inflamed liver (hepatitis) or
- build-up of fluid in the abdomen (ascites)

However, your doctor may decide that you must take Roximstad to deal with your infection. In this case, you will be given half of the usual dose per day. i.e. 150 mg roxithromycin.

Use in children

Children below 6 years of age should not use Roximstad tablets. Different forms of roxithromycin are available for young children. For example an oral suspension.

Duration of treatment

Your doctor will tell you for how long you should take Roximstad. For some infections treatment will last for at least 10 days.

You will usually be asked to take Roximstad for a further 3 or 4 days after your symptoms have improved.

It is important to always take the tablets for as long as your doctor tells you to.

If you take more Roximstad than you should

If you have taken too many tablets contact your doctor or a pharmacist.

Remember to take the package and any remaining tablets with you.

Overdose with Roximstad may cause the following symptoms:

- feeling sick (nausea)
- being sick (vomiting)
- runny stools (diarrhoea)
- headache
- dizziness

Your doctor will treat the symptoms of Roximstad overdose.

If you forget to take Roximstad

If you forget to take a dose of Roximstad, just take the next dose at the usual time. Do not take a double dose to make up for a forgotten dose.

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

4. Possible side effects

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

Once-daily dosing (1 x 300 mg Roximstad tablets) gives more side effects than twice-daily dosing (2 x 150 mg Roximstad tablets).

Stop taking the medicine and contact your doctor immediately if you get:

Uncommon (may affect up to 1 in 100 people):

- Severe skin reactions such as
 - Erythema multiforme. This may cause spots, red welts or purple or blistered areas.

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

- Symptoms of angioedema (a life-threatening reaction), such as:
 - Swollen face, tongue or throat
 - Difficulty in swallowing
 - Hives and difficulty breathing

Not known (frequency cannot be estimated from the available data):

- Inflammation of the bowel causing abdominal pain or diarrhoea (pseudomembranous colitis)
- Serious skin reactions such as
 - Toxic epidermal necrolysis (TEN). This may cause a red rash over many parts of the body and loss of the outer layer of skin
 - Stevens-Johnson syndrome, which may cause a red or purplish rash that spreads and blisters, eventually causing the top layer of your skin to die and shed. Other symptoms include fever, chills, headaches and tiredness.
 - Exanthematous pustulosis, a red, scaly rash with bumps under the skin and blisters
- Potentially fatal inflammation of the pancreas, characterised by abdominal pain, nausea, vomiting, diarrhoea, fever and shock (haemorrhagic pancreatitis)
- Severe allergic (hypersensitivity) reactions (anaphylactic shock)
- Severe reduction in number of white blood cells which makes infections more likely (agranulocytosis)

Roximstad can also cause the following side effects:

Please consult your doctor in regular intervals as requested. This will help to detect possible side effects. Please inform your doctor during the routine examination, if you experience or experienced a possible side effect.

Common (may affect up to 1 in 10 people):

- Feeling sick (nausea)
- Pain in the upper middle part of the abdomen (epigastric pain)
- Headache
- Dizziness
- Upset stomach (dyspepsia)
- Runny stools (diarrhoea)
- Rash

Uncommon (may affect up to 1 in 100 people):

- Being sick (vomiting)
- Severe constipation (obstipation)
- Wind (flatulence)
- Changes in liver function as shown by blood tests (increased liver enzyme levels)
- Redness of the skin
- Hives (urticaria)
- Increase of certain white blood cells, detected by blood test (eosinophilia)

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

- Changes in blood count
- Allergic (hypersensitivity) reactions such as anaphylaxis
- Taste disorders (dysgeusia) including loss of sense of taste (ageusia)
- Smell disorders (parosmia) including loss of sense of smell (anosmia)
- Wheezing or difficulty in breathing (bronchospasm)
- Failure of bile to flow from the liver properly. This causes build-up of bile in the liver and liver damage (cholestatic hepatitis)
- Sudden inflammation of the liver (hepatitis)

- Inflammation of the pancreas (pancreatitis)
- A skin disease with redness, itching and flaking of the skin (eczema)
- Weakness
- Discomfort

Not known (frequency cannot be estimated from the available data):

- Infections with resistant bacteria or fungi (if you take Roximstad long-term)
- A reduced number of platelets in the blood (thrombocytopenia)
- Confusion
- Seeing or hearing things that are not there (hallucinations)
- Mental disorder where you lose contact with reality (psychosis)
- Pins and needles (paraesthesia)
- Impairment of vision
- Problems with your eye sight (blurred vision)
- Irregular heartbeat (QT prolongation)
- Rapid heartbeat (ventricular tachycardia)
- Problems with conduction of the heartbeat (torsades de pointes)
- Loss of appetite (anorexia)
- Yellowing of the skin or the whites of the eyes (jaundice)
- Itching (pruritus)
- A nerve disorder causing muscle weakness (myasthenia gravis)
- Low number of white blood cells (neutropenia)
- Purple or red pinpoint spots in the skin or mucous membranes caused by minor haemorrhage (purpura)
- Transitory deafness
- Impaired hearing (hypoacusis)
- A feeling of dizziness or “spinning” (vertigo)
- Ringing in the ears (tinnitus)

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 Roximstad

Keep this medicine out of the sight and reach of children.

Do not store Roximstad above 30 °C.

Do not use this medicine after the expiry date which is stated on the carton. 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 protect the environment.

6. Contents of the pack and other information

What Roximstad contains

The active substance is roxithromycin.

One Roximstad 150 mg film-coated tablet contains 150 mg roxithromycin.

One Roximstad 300 mg film-coated tablet contains 300 mg roxithromycin.

The other ingredients in the tablet core are:

- Microcrystalline cellulose
- Anhydrous colloidal silica
- Croscarmellose sodium
- Polaxamer 188
- Povidone
- Talc
- Magnesium stearate

The other ingredients in the film coating are:

- Lactose monohydrate
- Hypromellose
- Macrogol 4000
- Titanium dioxide (E171)

What Roximstad 150 mg and 300 mg film-coated tablets look like and contents of the pack

Roximstad 150 mg film-coated tablets are white, with an off-white core, round and biconvex in shape and bevelled.

Roximstad 300 mg film-coated tablets are white, with an off-white core, oblong and capsule-shaped, with a break line on one side.

Roximstad film-coated tablets are packaged in PVC/aluminium blister packs containing:

150 mg tablets

- 5, 10, 12, 14, 16, 20, 28, 30, 50, 60, 90, 100, 250 and 500 tablets.

300 mg tablets

- 5, 6, 7, 10, 14, 16, 20, 28, 30, 50, 60, 90, 100, 250 and 500 tablets.

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

[To be completed nationally]

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