

PACKAGE LEAFLET: INFORMATION FOR THE USER

Roxithromycin Sandoz, 150 mg, film-coated tablets **Roxithromycin Sandoz, 300 mg, film-coated tablets**

Roxithromycin

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

- 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. Do 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 gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

In this leaflet:

1. What Roxithromycin Sandoz is and what it is used for
2. Before you take Roxithromycin Sandoz
3. How to take Roxithromycin Sandoz
4. Possible side effects
5. How to store Roxithromycin Sandoz
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1. What Roxithromycin Sandoz is and what it is used for

Roxithromycin belongs to the group of macrolide antibiotics that stops the growth of certain bacteria.

Roxithromycin Sandoz is used to **treat** certain kinds of the following **infections**:

- inflammation of the tonsils, throat and middle ear
- chest infections such as pneumonia
- infections of the skin and surrounding tissues
- infections of the urethra, the organ used when passing urine
- infections of genital organs such as the neck of the womb

2. Before you take Roxithromycin Sandoz

Do NOT take Roxithromycin Sandoz

if you

- are **allergic** (hypersensitive) to roxithromycin, other macrolide antibiotics or to any of the other ingredients
- or any family member have changes in the electrical activity of the heart called “**QT-prolongation**”

- are taking
 - **ergotamine** or **dihydroergotamine**, medicines to treat migraine
 - **cisapride**, a medicine to treat stomach or bowel problems
 - **pimozide**, a medicine to treat psychoses
 - **astemizole** and **terfenadine**, medicines to treat allergies.

Take special care with Roxithromycin Sandoz

Inform your doctor if any of the following applies to you before taking this medicine:

- **liver problems**
Do not take Roxithromycin Sandoz unless your doctor has specifically recommended it. Your doctor may check liver values and reduce the dose as describes in section 3. How to take Roxithromycin Sandoz.
- **heart problems**, such as
 - chest pain due to narrowing of the coronary arteries of the heart muscle
 - heart failure,
 - very slow heart rate, less than 50 beats per minute,
 - a history of irregular heart beat
- low **potassium** or **magnesium levels** in the blood
- a certain type of muscle weakness called **myasthenia gravis**
- children and people with a **body weight less than 40 kg**
- you develop **severe persistent (bloody) diarrhoea**
You may have an inflammation of the large intestine caused by the use of roxithromycin. In that case, the use of Roxithromycin Sandoz **must be stopped immediately**. Do not take medicines that reduce bowel movements.
- taking **other medicines** - see next section.

Your doctor may decide to do tests on your kidneys, liver and blood if you are given Roxithromycin Sandoz for longer than 14 days.

Taking other medicines

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

The effects of the following medicines can be influenced by Roxithromycin Sandoz:

- **ergotamine** or **dihydroergotamine**, medicines to treat migraine
- **cisapride**, a medicine to treat stomach or bowel problems
- **pimozide**, a medicine to treat psychoses
- **astemizole** and **terfenadine**, medicines to treat allergies

Do not take Roxithromycin Sandoz together with these medicines above.

- medicines, which can cause a certain heart abnormality known as QT prolongation
- **cyclosporin**, a medicine to prevent transplant rejection
Your doctor will check your blood levels regularly and may adjust the cyclosporine dose.
- **contraceptive pills**
In rare cases and especially if vomiting and diarrhoea occur, the contraceptive effects can be unreliable. Using an additional form of contraception, such as condoms, during

Roxithromycin treatment is therefore advisable.

- medicines to treat heart weakness, such as **digitoxin, digoxin**
- **disopyramide**, a medicines to treat heart rhythm disturbances
Your doctor may monitor the concentrations of disopyramide in the blood.
- **ketoconazole**, a medicine to treat fungal infections
- **midazolam**, a medicine to tranquillise, induce sleep and/or relax muscles
- certain HIV medicines called **protease inhibitors**
- **theophylline**, a medicine to treat asthma
Your doctor may monitor the concentrations of theophylline in the blood.
- blood-thinning medicines, such as **warfarin, phenprocoumon**
Check-ups for blood clotting should be made more often when Roxithromycin Sandoz is also being used.

Taking Roxithromycin Sandoz with food and drink

Take the tablets at least 15 minutes before meals. This helps to absorb the medicine properly from the gut.

Pregnancy and breastfeeding

If you are pregnant or breastfeeding, **only** use Roxithromycin Sandoz **if your doctor indicates it is absolutely necessary**.

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

Driving and using machines

Roxithromycin Sandoz is unlikely to impair the ability to drive and operate machinery. However, the side effect dizziness may occur more often when beginning therapy. Be careful when driving or operating machinery if this symptom occurs.

Important information about some of the ingredients of Roxithromycin Sandoz

This medicine contains **lactose**. If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicine.

3. How to take Roxithromycin Sandoz

Always take Roxithromycin Sandoz exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure.

The usual dose is:

- **Adults and children weighing 40 kg or more:**
Roxithromycin Sandoz, 150 mg
- **1 tablet each morning and 1 tablet each evening**
Patients with pneumonia may alternatively take 2 tablets once daily.
- maximum dose: 2 tablets per day

Roxithromycin Sandoz, 300 mg

- patients with pneumonia: **1 tablet once daily**

- maximum dose: 1 tablet per day

Dosage adjustment is not necessary for patients over 65 years.

- **Children weighing less than 40 kg** should not use these tablets.

Reduced liver function

Your doctor may reduce the dose or choose another medicine if your liver function is severely reduced.

How to use

Take the tablets with one glass of water at least 15 minutes before meals.

How long to use Roxithromycin Sandoz

The doctor will decide this depending on the infection.

- Treatment should be continued for at least 3-4 days after symptoms have stopped.
- Treatment should be continued for at least 10 days in the case of certain infections, such as tonsil or throat infections, to prevent relapse or further complications.

If you take more Roxithromycin Sandoz than you should

Please contact your doctor or a hospital immediately. Take your medicine with you to show the doctor what you have taken.

Symptoms of overdose are nausea, vomiting and diarrhea. Headache and dizziness may also appear.

If you forget to take Roxithromycin Sandoz

If you miss a dose, take it as soon as possible. Then continue treatment with the prescribed dose at the usual time. **Do not take a double dose** to make up for a forgotten dose.

If you stop taking Roxithromycin Sandoz

Always take Roxithromycin Sandoz for as long as your doctor has recommended it, even when you feel better.

If you stop taking the tablets too soon it can trigger a recurring and more resistant infection.

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

4. Possible side effects

Like all medicines, Roxithromycin Sandoz can cause side effects, although not everybody gets them.

In **rare** cases (affects 1 to 10 users in 10,000 users) life-threatening side effects can occur, such as

- **severe allergic reaction** with the following signs:
 - sudden breathing and swallowing difficulties

- swelling of the face, tongue and/or larynx
- extreme dizziness or collapse
- severe or itchy skin rash

See also section 2 “Do not take Roxithromycin Sandoz”.

Other life-threatening side effects can occur (frequency not known), such as

- severe and persistent **diarrhoea** during or in the first weeks after treatment with occasional bloody mucous and/or cramp-like stomach pain.

This could indicate serious bowel inflammation.

Do not take medicines that reduce bowel movements.

- severe skin rash, showing blistering, peeling and pain in the eyes, mouth or genital organs.

Stop treatment and contact your doctor or nearest hospital if any of the two points above apply to you.

Other side effects:

Common, affects 1 to 10 users in 100:

- nausea
- stomach pain

Uncommon, affects 1 to 10 users in 1,000:

- headache, dizziness
- vomiting
- indigestion, constipation, wind,
- diarrhea, see also above.
- allergic reactions which are mainly skin and mucous membrane reactions such as:
 - reddening
 - swelling, with and without itching or small bleeding spots
- increase in liver levels in the blood such as bilirubin and enzymes called transaminases, alkaline phosphatase

Rare, affects 1 to 10 users in 10,000:

- changes in blood count
- liver inflammation with bile congestion and jaundice
- reversible pancreas inflammation during or after treatment, causing severe stomach and back pain.
- impaired sense of taste and/or smell
- ringing in the ear
- cramps in the airways (bronchospasm)
- itchy skin rash
- weakness, discomfort

Frequency not known:

- changes in the electrical activity of the heart known as “QT prolongation”
- rapid or irregular heart beat

- reduced number of blood platelets (may cause easy bruising or bleeding)
- tingling and numbness in the hands and feet
- muscle weakness (myasthenia gravis)
- vision disorders
- loss of appetite
- itching
- fungal infections, such as in the mouth and vagina on long-term use
- yellowing of the skin or whites of the eyes caused by liver or blood problems (jaundice)
- confusion, hallucination, mental disorders

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

5. How to store Roxithromycin Sandoz

Keep out of the reach and sight of children.

This medicinal product does not require any special storage conditions.

Do not use Roxithromycin Sandoz after the expiry date which is stated on the carton and the blister pack after EXP. The expiry date refers to the last day of that month.

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 Roxithromycin Sandoz contains

The **active substance is roxithromycin**.

Roxithromycin Sandoz, 150 mg

Each film-coated tablet contains 150 mg roxithromycin.

Roxithromycin Sandoz, 300 mg

Each film-coated tablet contains 300 mg roxithromycin.

The other ingredients are:

Core: microcrystalline cellulose, colloidal anhydrous silica, croscarmellose sodium, polaxamer 188, povidone, talc, magnesium stearate.

Coating: lactose monohydrate, hypromellose, macrogol 4000, titanium dioxide (E171)

What Roxithromycin Sandoz looks like and contents of the pack

Roxithromycin Sandoz, 150 mg] is a round white, biconvex bevelled film-coated tablet with off white core.

Roxithromycin Sandoz, 300 mg] is an oblong white, capsule shaped film-coated tablet with off white core.

Roxithromycin Sandoz, 150 mg]

PVC aluminium blister: 5, 10, 12, 14, 15, 16, 20, 28, 30, 50, 60, 90, 100, 250 and 500 tablets

Roxithromycin Sandoz, 300 mg]

PVC aluminium blister: 5, 6, 7, 10, 14, 15, 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]>

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

This leaflet was last approved in 19 May 2010

<[To be completed nationally]>