

BIAXSIG®

(bi-ax-sig)

Roxithromycin (rocks-e-throw-my-sin)

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about Biaxsig. It does not contain all the available information.

It does not take the place of talking to your doctor and pharmacist.

All medicines have risks and benefits. Your doctor has weighed the risks of you taking this medicine against the benefits they expect it will have for you.

If you have any concerns about taking this medicine, ask your doctor or pharmacist. Keep this leaflet with the medicine.

You may need to read it again.

What Biaxsig is used for

Biaxsig is used to treat infections in different parts of the body caused by bacteria. For example:

- acute pharyngitis (sore throat and discomfort when swallowing)
- tonsillitis
- sinusitis
- acute bronchitis (infection of the bronchi causing coughing)
- exacerbation of chronic bronchitis
- pneumonia (lung infection characterised by fever, malaise, headache)
- skin and soft tissue infections
- non gonococcal urethritis
- impetigo (bacterial infection causing sores on the skin)

Biaxsig is an antibiotic that belongs to a group of medicines called macrolides.

These antibiotics work by killing or stopping the growth of the bacteria that are causing your infection.

Biaxsig, like other antibiotics, does not work against viral infections such as the flu.

Your doctor may have prescribed Biaxsig for another reason. Ask your doctor if you have any questions about why it has been prescribed for you.

This medicine is available only with a doctor's prescription.

This medicine is not addictive.

Before you take it

When you must not take it

Do not take Biaxsig if you have severe liver problems.

Do not take Biaxsig if you have an allergy to:

- roxithromycin or any other macrolide antibiotic eg azithromycin, clarithromycin or erythromycin.
- any of the ingredients listed at the end of this leaflet (see Product Description)

Symptoms of an allergic reaction may include skin rash, itching, shortness of breath or swelling of the face, lips or tongue which cause difficulty in swallowing or breathing.

Do not take Biaxsig if you are taking certain medicines for migraine headache called ergot alkaloids eg Cafergot, Dihyergot; (not all brands listed).

Ask your doctor if you are not sure if you are taking one of these medicines.

Do not take it after the expiry date (EXP) printed on the pack.

If you take it after the expiry date has passed, it may not work as well.

Do not take it if the packaging is damaged or shows signs of tampering.

Before you start to take it

Tell your doctor or pharmacist if you have allergies to any other substances, such as foods, preservatives or dyes.

Tell your doctor or pharmacist if you are pregnant or intend to become pregnant.

Like most medicines of this kind, Biaxsig is not recommended for use during pregnancy. Your doctor or pharmacist will discuss the risks and benefits of taking it if you are pregnant.

Tell your doctor or pharmacist if you are breastfeeding or plan to breastfeed.

Biaxsig passes into breast milk. Your doctor or pharmacist will discuss the risks and benefits of taking it if you are breastfeeding or planning to breastfeed.

Tell your doctor or pharmacist if you have or have ever had any other medical conditions, especially the following:

- kidney problems (impaired function)
- liver problems (hepatic cirrhosis with jaundice and /or ascites).

Tell your doctor or pharmacist if you plan to have surgery.

If you have not told your doctor or pharmacist about any of the above, tell them before you take Biaxsig.

Use in the Elderly

Biaxsig can be used in the elderly with no dosage adjustment required.

Taking other medicines

Tell your doctor or pharmacist if you are taking any other medicines, including medicines that you buy without a prescription from your pharmacy, supermarket or health food shop.

Some medicines may be affected by Biaxsig, or may affect how well Biaxsig works. These include:

- theophylline (Neulin), a medicine used to treat asthma
- some medicines for migraine headache such as ergotamine (Cafergot) or dihydroergotamine (Dihyergot tablets)
- disopyramide (Rythmodan), a medicine to treat irregular heart rhythms
- terfenadine and astemizole, over the counter medicines used to treat allergies
- warfarin (Coumadin, Marevan), a medicine used to prevent blood clots
- digoxin (Lanoxin, Sigmaxin), a medicine used to treat heart failure
- midazolam (Hypnovel, Midazolam Sandoz), used to induce sleep before operations

- ciclosporin (Neoral, Cicoral, Cysporin, Sandimmun), a medicine used to prevent organ transplant rejection or to treat certain problems with the immune system
- cisapride, a medicine used to treat gastrointestinal problems
- pimozide (Orap), an antipsychotic medicine

These medicines may be affected by Biaxsig, or may affect how well it works. You may need different amounts of your medicine, or you may need to take different medicines. Your doctor or pharmacist will advise you.

Your doctor or pharmacist has more information on medicines to be careful with or avoid while taking Biaxsig.

How to take it

How much to take

The recommended adult dosage is 300 mg per day which may be taken according to one of the following alternative dosage regimens:

- one 300 mg tablet once a day, or
- one 150 mg tablet twice a day, or
- two 150 mg tablets once a day

However, depending on your condition and how you react to the medicine, your doctor may ask you to take a different dose.

The recommended dosage for children more than 40 kg is one 150 mg tablet twice daily.

The dosage of Biaxsig given to children is dependent on the child's weight.

Ask your doctor or pharmacist if you are unsure of the correct dose for you.

They will tell you exactly how much to take.

Follow the instructions they give you.

If you take the wrong dose, Biaxsig may not work as well and your problem may not improve.

How to take it

Swallow the tablets whole with a glass of water.

When to take it

Biaxsig should be taken at least 15 minutes before food or on an empty stomach (ie more than 3 hours after a meal).

Biaxsig works best if you take it on an empty stomach.

How long to take it

For treating infections, Biaxsig is usually taken for 5 to 10 days.

However, your doctor may prescribe Biaxsig for longer periods.

Continue taking the tablets until you finish the pack or until your doctor or pharmacist tells you to stop.

Ask your doctor or pharmacist if you are not sure how long to take the medicine for.

If you forget to take it

Do not try to make up for missed doses by taking more than one dose at a time.

This may increase the chance of getting an unwanted side effect.

If it is almost time for your next dose, skip the dose you missed and take the next dose when you are meant to.

Do not take a double dose to make up for the dose you have missed.

If there is still a long time to go before your next dose, take it as soon as you remember, and then go back to taking it as you would normally.

If you are not sure what to do, ask your doctor or pharmacist.

If you have trouble remembering when to take your medicine, ask your pharmacist for hints.

If you take too much (overdose)

Immediately telephone your doctor or Poisons Information Centre (13 11 26), or go to the Emergency Department at your nearest hospital, if you think that you or anyone else may have taken too much Biaxsig.

Do this even if there are no signs of discomfort or poisoning. You may need urgent medical attention.

While you are taking it

Things you must do

If the symptoms of your infection do not improve within a few days, or if they become worse, tell your doctor.

If you get severe diarrhoea tell your doctor, pharmacist or nurse immediately. Do this even if it occurs several weeks after Biaxsig has been stopped.

Diarrhoea may mean that you have a serious condition affecting your bowel. You may need urgent medical care. Do not take any diarrhoea medicine without first checking with your doctor.

If you get a sore, white mouth or tongue while taking, or soon after stopping Biaxsig, tell your doctor or pharmacist. Also tell your doctor or pharmacist if you get vaginal itching or discharge.

This may mean you have a fungal/yeast infection called thrush. Sometimes the use of Biaxsig allows fungi/yeast to grow and the above symptoms to occur. Biaxsig does not work against fungi/yeast.

Tell all the doctors, dentists and pharmacists who are treating you that you are taking Biaxsig.

If you are about to start taking any new medicine, tell your doctor and pharmacist that you are taking Biaxsig.

If you plan to have surgery that needs a general anaesthetic tell your doctor or dentist that you are taking this medicine.

If you become pregnant while you are taking Biaxsig, tell your doctor or pharmacist immediately.

Things you must not do

Do not take more than the recommended dose unless your doctor or pharmacist tells you to.

Do not give this medicine to anyone else, even if they have the same condition as you.

Do not use this medicine to treat any other complaints unless your doctor tells you to.

Do not stop taking your tablets because you are feeling better, unless advised by your doctor or pharmacist.

If you do not complete the full course prescribed by your doctor, all of the bacteria causing your infection may not be killed.

These bacteria may continue to grow and

multiply so that your infection may not clear completely or it may return.

Side Effects

All medicines have some unwanted side effects. Sometimes they are serious, but most of the time they are not. Your doctor or pharmacist has weighed the risks of using this medicine against the benefits they expect it will have for you.

Do not be alarmed by this list of possible side effects.

You may not experience any of them.

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are taking Biaxsig.

It helps most people with bacterial infections, but it may have unwanted side effects in a few people.

Tell your doctor or pharmacist if you notice any of the following and they worry you:

- oral thrush - white, furry, sore tongue and mouth
- vaginal thrush - sore and itchy vagina and/or discharge
- nausea, vomiting, stomach pain, indigestion, diarrhoea, flatulence
- loss of appetite
- red and/or itchy skin
- headache, dizziness, ringing in the ears
- hallucinations
- confusion
- tiredness
- altered taste
- rash
- blurred vision and/or visual impairment

These side effects are usually mild and short-lived.

Tell your doctor or pharmacist immediately if you notice any of the following, particularly if they occur several weeks after stopping treatment with Biaxsig:

- severe abdominal cramps or stomach cramps
- watery and severe diarrhoea, which may sometimes be bloody
- fever, in combination with one or both of the above.

These are rare but serious side effects. You may have a serious condition affecting your bowel. Therefore, you may need urgent medical attention.

Do not take any diarrhoea medicine without first checking with your doctor.

If any of the following happen, stop taking this medicine and tell your doctor immediately, or go to Accident and Emergency at your nearest hospital:

- frequent infections such as fever, severe chills, sore throat or mouth ulcers
- severe persistent diarrhoea
- swelling of the face, lips, mouth and tongue
- difficulty in swallowing or breathing
- an allergic reaction (for example, itchy skin, rash, swelling, asthma)
- severe blisters and bleeding in the lips, eyes, mouth, nose and genitals
- severe skin rash

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

Tell your doctor or pharmacist if you notice anything else that is making you feel unwell.

Other side effects not listed above may occur in some consumers.

Do not be alarmed by this list of possible side effects.

You may not experience any of them.

Ask your doctor or pharmacist to answer any questions you may have.

After taking it

If you have any queries about any aspect of your medicine, or any questions regarding the information in this leaflet, discuss them with your doctor or pharmacist.

Storage

Keep your tablets in the blister pack until it is time to take them.

If you take the tablets out of the blister pack, they may not keep well.

Keep the medicine in a cool dry place where the temperature stays below 25°C.

Do not store it or any other medicine in the bathroom, near a sink or on a window sill.

Do not leave it in the car.

Heat and dampness can destroy some medicines.

Keep it where children cannot reach it.

A locked cupboard at least one-and-a-half metres above the ground is a good place to store medicines.

Disposal

If your doctor tells you to stop taking the tablets or the tablets have passed their expiry date, ask your pharmacist what to do with any tablets that are left over.

Product description

What it looks like

Biaxsig 300 mg and 150 mg tablets are round white film coated tablets. Each blister pack contains either 5 tablets (300 mg strength) or 10 tablets (150 mg strength).

Ingredients

Active Ingredients:

Each Biaxsig tablet contains either 150 mg or 300 mg of the active ingredient roxithromycin.

Inactive Ingredients:

Each tablet also contains:

- hypromellose
- poloxamer
- povidone
- colloidal anhydrous silica
- magnesium stearate (470)
- purified talc (553)
- maize starch
- hypromellose
- glucose
- titanium dioxide (171)
- propylene glycol (1520)

Biaxsig does not contain gluten, lactose, sucrose, tartrazine or any other azo dyes.

Manufacturer/Sponsor

Biaxsig tablets are manufactured for:

sanofi aventis australia pty ltd

12-24 Talavera Road

Macquarie Park NSW 2113

Australian Registration Numbers

Biaxsig 150 mg tablets:

AUST R 49134

Biaxsig 300 mg tablets:

AUST R 49135

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