

# ROXITHROMYCIN SCP

Roxithromycin

## Consumer Medicine Information

### What is in this leaflet

This leaflet answers some common questions about this medicine.

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 roxithromycin 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 ROXITHROMYCIN is used for

Roxithromycin 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)
- pneumonia (lung infection characterised by fever, malaise, headache)
- skin and soft tissue infections
- non gonococcal urethritis
- impetigo (bacterial infection causing sores on the skin)

Roxithromycin 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.

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

**Your doctor may have prescribed roxithromycin 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.

Roxithromycin is not addictive.

### Before you take ROXITHROMYCIN

#### When you must not take it

#### Do not take roxithromycin if:

1. 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).Some of the symptoms of an allergic reaction may include shortness of breath, wheezing or difficulty breathing; swelling of the face, lips, tongue or other parts of the body; rash, itching or hives on the skin.
2. you have severe liver problems
3. you are taking certain medicines for migraine headache called ergot alkaloids (eg., Migral, Cafergot, Ergodryl, Dihydroergot; [not all brands listed])  
Ask your doctor if you are not sure if you are taking one of these medicines.

4. the packaging is torn or shows signs of tampering
5. the expiry date on the pack has passed.  
If you take this medicine after the expiry date has passed, it may not work as well.

**If you are not sure whether you should start taking roxithromycin, talk to your doctor.**

#### Before you start to take it

#### Tell your doctor if:

1. you are pregnant or intend to become pregnant  
Your doctor will discuss the risks and benefits of using roxithromycin during pregnancy.
2. you are breast-feeding or plan to breast-feed  
Roxithromycin passes into the breast milk. Your doctor will discuss the risks and benefits of using roxithromycin while breast-feeding.
3. you have or have ever had any other health problems/medical conditions, including:
  - kidney problems (impaired function)
  - liver problems (hepatic cirrhosis with jaundice and/or ascites)
4. you have any allergies to any other medicines or any other substances, such as foods, preservatives or dyes.

**If you have not told your doctor about any of the above, tell him/her before you take roxithromycin.**

#### Use in the elderly

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

#### Taking other medicines

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

There may be interference between roxithromycin and some other medicines, including:

- theophylline (Neulin, Austyn, Theo-dur), a medicine used to treat asthma
- some medicines for migraine headache such as ergotamine (Migral, Ergodryl, Cafergot) or dihydroergotamine (Dihydroergot tablets)
- disopyramide (Rythmodan), a medicine to treat irregular heart rhythms
- terfenadine (Teldane) and astemizole (Hismanal), over the counter medicines used to treat allergies
- warfarin (Coumadin, Marevan), a medicine used to prevent blood clots
- digoxin (Lanoxin), a medicine used to treat heart failure
- midazolam (Hypnovel), used to induce sleep before operations
- cyclosporin (Neoral, Sandimmun), a medicine used to prevent organ transplant rejection or to treat certain problems with the immune system
- cisapride (Prepulsid), a medicine used to treat gastrointestinal problems
- pimozide (Orap), an antipsychotic medicine

These medicines may be affected by roxithromycin, 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 has more information on medicines to be careful with or avoid while taking roxithromycin.

### How to take ROXITHROMYCIN

**Follow all directions given to you by your doctor and pharmacist carefully.**

They may differ from the information contained in this leaflet.

**If you do not understand the instructions on the box, ask your doctor or pharmacist for help.**

#### 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 roxithromycin given to children is dependant on the child's weight.

Roxithromycin is not recommended for children less than 40 kg in weight.

#### How to take it

Swallow roxithromycin tablets whole with a glass of water.

#### When to take it

Roxithromycin should be taken at least 15 minutes before food or on an empty stomach (that is, more than 3 hours after a meal). Roxithromycin works best if you take it on an empty stomach.

Take your medicine at about the same time each day. Taking it at the same time each day will have the best effect. It will also help you remember when to take it.

#### How long to take it

For treating infections, roxithromycin is usually taken for 5 to 10 days. However, your doctor may prescribe roxithromycin for longer periods.

**Check with your doctor if you are not sure how long you should be taking it.**

**Continue taking roxithromycin until you finish the pack or until your doctor recommends.**

#### If you forget to take it

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

Otherwise, take it as soon as you remember, and then go back to taking your tablets as you would normally.

**If you are not sure whether to skip the dose, talk to your doctor or pharmacist.**

**Do not double a dose to make up for the dose that you missed.**

*If you take too much (overdose)*

**Immediately telephone your doctor or Poisons Information Centre (13 11 26), or go to casualty at your nearest hospital, if you think that you or anyone else may have taken too much roxithromycin. Do this even if there are no signs of discomfort or poisoning. You may need urgent medical attention.**

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### While you are using ROXITHROMYCIN

#### *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 roxithromycin 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 roxithromycin, 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 roxithromycin allows fungi/yeast to grow and the above symptoms to occur. Roxithromycin does not work against fungi/yeast.

**If you become pregnant while you are taking roxithromycin, tell your doctor.**

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

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

#### *Things you must not do*

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

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.

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

**Do not use roxithromycin to treat any other complaints unless your doctor tells you to.**

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### Side effects

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

Roxithromycin helps many people with bacterial infections, but it may have unwanted side effects in some people.

All medicines can have side effects. Sometimes they are serious, most of the time they are not. Medical treatment may be required for some of the side effects.

**Ask your doctor or pharmacist to answer any questions you may have regarding side effects.**

#### *While taking it*

**Tell your doctor 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, diarrhoea, flatulence
- loss of appetite
- red and/or itchy skin
- headache, dizziness, ringing in the ears
- tiredness
- altered taste

**Tell your doctor immediately or go to casualty at your nearest hospital if you notice any of the following:**

- swelling of the face, lips, mouth and tongue; difficulty breathing or asthma
- an allergic reaction (for example, itchy skin, rash, swelling, asthma)
- severe persistent diarrhoea

These may be signs of a serious allergic reaction.

**Other side effects not listed above may also occur in some patients. Tell your doctor if you notice any other effects.**

#### *After finishing it*

**Tell your doctor immediately if you notice any of the following side effects, particularly if they occur several weeks after stopping treatment with roxithromycin:**

- severe abdominal cramps or stomach cramps
- watery and severe diarrhoea, which may also 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. However, this side effect is rare.

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

Some people may get other side effects while taking roxithromycin.

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

Most people do not experience any of them.

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### After taking ROXITHROMYCIN

#### *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 roxithromycin in a cool dry place where the temperature stays below 25°C.**

**Do not store it or any other medicine in the bathroom or near a sink. Do not leave it in the car or on window sills.**

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.

#### *Where to go for further information*

Pharmaceutical companies are not in a position to give people an individual diagnosis or medical advice. Your doctor or pharmacist is the best person to give you advice on the treatment of your condition.

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### Product description

#### *What it looks like*

ROXITHROMYCIN SCP 150 mg and 300 mg tablets are white to off-white round convex and film coated. Each blister pack contains either 5 tablets (300 mg strength) or 10 tablets (150 mg strength).

#### *Ingredients*

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

The tablets also contain the following inactive ingredients:

- maize starch,
- hydroxypropylcellulose,
- silica - colloidal anhydrous,
- sodium starch glycollate,
- poloxamer,
- povidone,
- magnesium stearate,
- talc - purified,
- propylene glycol,
- glucose,
- titanium dioxide, and
- hypromellose.

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

#### *Manufacturer/Distributor*

ROXITHROMYCIN SCP tablets are manufactured for:

**Southern Cross Pharma Pty Ltd**

56 Illabunda Drive

Malua Bay

NSW 2536

Australia

Date of preparation:

17 February 2012

#### **Australian Registration Numbers:**

ROXITHROMYCIN SCP 150 mg 133756

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