Rulide(R)

(roo-lied)

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

Consumer Medicine Information (CMI)

What is in this leaflet

This leaflet answers some common questions about Rulide.

It does not contain all the available information. It does not take the place of talking to your doctor or pharmacist.

All medicines have risks and benefits. Your doctor or pharmacist 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 Rulide is used for

Rulide 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 gonoccocal urethritis
* impetigo (bacterial infection causing sores on the skin)

Rulide 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.

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

Your doctor, however, may prescribe Rulide for another purpose.

Ask your doctor or pharmacist 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 Rulide if you have severe liver problems.

Do not take Rulide if you have 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

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

Do not Rulide if you are also taking certain medicines for migraine headache called ergot alkaloids eg Migral, Cafergot, Ergodryl, Dihydergot (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, Rulide 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 planning to breastfeed.

Rulide 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 had any 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 Rulide.

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 store.

Some medicines may interfere with the absorption of Rulide. These include:

* theophylline (Neulin, Austyn, Theo-dur), a medicine used to treat asthma
* some medicines for migraine headache such as ergotamine (Migral, Ergodryl, Cafergot) or dihydroergotamine (Dihydergot 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, Sigmaxin), a medicine used to treat heart failure
* midazolam (Hypnovel, Midazolam Sandoz), used to induce sleep before operations
* cyclosporin (Neoral, Cicoral, Cysporin, 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 Rulide, or may affect how well it works. You may need to use different amounts of your medicine or take different medicines. Your doctor or pharmacist will advise you.

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

How to take it

How much to take

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

* one 300mg tablet once a day, or
* one 150mg tablet twice a day, or
* two 150mg 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 40kg is one 150mg tablet twice daily.

The dosage of Rulide given to children is dependant on the child's weight.

Rulide D should be used for children less than 40kg in weight.

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

They will tell you exactly how many to take.

Follow the instructions they give you.

If you take the wrong dose, Rulide 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

Take Rulide at least 15 minutes before food or on an empty stomach ie more than 3 hours after a meal.

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

How long to take it

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

However, your doctor may prescribe Rulide 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 the Poisons Information Centre (telephone Australia 13 11 26 or New Zealand 0800 POISON or 0800 764766), or go to the Accident and Emergency at your nearest hospital if you think that you or anyone else may have taken too much Rulide.

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 or pharmacist.

If you get severe diarrhoea tell your doctor, pharmacist or nurse immediately. Do this even if it occurs several weeks after Rulide 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 Rulide, 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 Rulide allows fungi/yeast to grow and the above symptoms to occur. Rulide does not work against fungi/yeast.

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

If you are about to be started on any new medicine, tell your doctor and pharmacist that you are taking Rulide.

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 Rulide, 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 or pharmacist 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 Rulide.

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

These are mild side effects of this medicine and usually 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 Rulide:

* 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.

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:

* severe persistent diarrhoea
* swelling of the face, lips, mouth and tongue
* an allergic reaction (for example, itchy skin, rash, swelling, asthma)

These are very serious side effects. If you have them, you may have had a serious allergic reaction to Rulide. 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 30 degrees C.

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

Do not leave it in the car.

Heat and damp 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 or pharmacist tells you to stop taking Rulide, or the medicine has passed its expiry date, ask your pharmacist what to do with any that are left over.

Return any unused medicine to your pharmacist.

Product description

What it looks like

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

Ingredients

Active Ingredient

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

Inactive Ingredients

Each tablet also contains:

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

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

Manufacturer/Sponsor

Rulide is made in France.

Rulide is supplied in Australia by:
sanofi-aventis australia pty ltd
12-24 Talavera Road
Macquarie Park NSW 2113

Rulide is supplied in New Zealand by:
sanofi-aventis new zealand limited
Level 8, James and Wells Tower
56 Cawley Street
Ellerslie
Auckland

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150mg tablets: AUST R 39409
300mg tablets: AUST R 42565
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