

Rulide[®] D

(roo-lyed)

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

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about Rulide D.

It does not contain all the available information.

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

Your doctor or pharmacist has weighed the benefits of your child taking Rulide D against any possible risk.

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 is Rulide D used for

Rulide D is used mainly to treat respiratory tract infections, and skin and soft tissue infections.

However, your doctor may have prescribed Rulide D for another reason.

Ask your doctor if you have any questions about why Rulide D has been prescribed for your child.

Rulide D (roxithromycin) is an antibiotic, which belongs to a group of medicines called macrolides.

These antibiotics work by killing the bacteria that are causing the infection. Like all antibiotics Rulide D will not work against viral infections.

Before you take Rulide D

Rulide D must not be taken if:

- 1. your child has an allergy to:**
 - * roxithromycin or any other macrolide eg erythromycin, clarithromycin or azithromycin
 - * any of the ingredients listed at the end of this leaflet (see Product Description)Symptoms of an allergic reaction may include skin rash, itching, difficulty breathing or swelling of the face, lips or tongue, which cause difficulty in swallowing or breathing.
- 2. your child has severe liver problems**
- 3. your child is taking certain medicines for migraine headache called ergot alkaloids**
- 4. if the packaging is torn or shows signs of tampering or if the expiry date on the pack has passed, please tell your pharmacist**

Before you start to take it

Tell your doctor or pharmacist if your child has or has ever had allergies to:

- * any other medicines
- * any other substances, such as foods, preservatives or dyes

Tell your doctor or pharmacist if your child has or has ever had any other health problems/ medical conditions, especially the

following:

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

Taking other medicines

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

Some medicines and Rulide D may interfere with each other. These include theophylline, disopyramide, warfarin, terfenadine, digoxin, midazolam, ciclosporin, cisapride, pimozone, and some migraine medicines.

Your doctor and pharmacist may have more information about medicines, which, if taken at the same time as Rulide D, may require a dosage adjustment.

How to take Rulide D

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

They may differ from the information contained in this leaflet.

How much to take

For children weighing less than 40 kg, the dosage can range from half a tablet, one tablet or two tablets

twice a day. Your doctor will tell you the correct number of tablets to give your child.

How to take it

Follow the instructions below on how to give your child Rulide D.

The number of tablets your doctor has recommended should be added to water.

1. Remove the correct number of tablets from the foil. If your child is only taking half a tablet at a time, place the remaining half of the tablet back in the foil and cover it up.
2. Add half, one or two tablets as directed by your doctor, to water and mix well. At least a spoonful of water should be used.
3. Wait about 30 or 40 seconds for the tablet to break down into fine granules. (The tablets will not completely dissolve). Stir if necessary.
4. Ensure the water and granules are swallowed by your child straight away, otherwise the pleasant strawberry taste of Rulide D may disappear.
5. Have a glass of water ready and give your child a drink immediately after taking the medicine to ensure all the Rulide D is swallowed.

When and how long to take it

Rulide D works best on an empty stomach so it should be taken at least 15 minutes before food or at least 3 hours after a meal.

Rulide D is usually taken for 5 to 10 days. Children should not take Rulide D for more than 10 days.

Ask you doctor if you are not sure how long your child should be taking it.

Make sure your child takes Rulide D for the number of days your doctor has prescribed, even if they begin to feel better after a few days. If the full course is not

finished, the infection may not clear completely or their symptoms may return.

If you forget to give a dose

Only give a missed dose if you remember it soon after the dose was due. Otherwise skip this dose altogether and go back to giving the medicine as you would normally.

Do not take a double dose to make up for the dose that was missed.

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

If you take too much (overdose)

Immediately telephone your doctor or pharmacist or the Poisons Information Centre (phone 13 11 26) or New Zealand 0800 POISON or (0800 764 766), or go to the Accident and Emergency Department at your nearest hospital, if you think that your child or anyone else may have taken too much Rulide D. Do this even if there are no signs of discomfort or poisoning.

Your child may need urgent medical attention.

While using Rulide D

Things you must do

If symptoms of your child's infection do not improve with a few days, or if they become worse, tell your doctor.

If your child is about to start taking any new medicine, tell your doctor or pharmacist that they are taking Rulide D.

Things you must not do

Rulide D has been prescribed for your child. Do not give to anyone else, even if they have the same condition as your child. Do not use Rulide D to treat any other complaints unless your doctor tells you to.

Side effects

Inform your doctor as soon as possible if your child has any problems while taking Rulide D, even if you do not think the problems are connected with the medicine or they are not listed in this leaflet.

Like other medicines, Rulide D can cause some side effects. If they occur, most are likely to be minor and temporary. However, some may be serious and need medical attention.

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

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

If any of the following happen, tell your doctor or pharmacist immediately or go to the Accident and Emergency Department at your nearest hospital:

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

These may be serious side effects or signs of a serious allergic reaction.

Tell your doctor immediately if you notice any of the following symptoms, particularly if they occur within several weeks of stopping treatment with Rulide D:

- * 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. Your child may have a serious condition affecting the bowel. Therefore, your child may need urgent medical attention.

Do not be alarmed by this list of possible side effects. Your child may not experience any of them.

Other side effects not listed above may occur.

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

Other side effects not listed above may occur.

After taking Rulide D

Tell your doctor immediately if you notice any of the following symptoms, particularly if they occur within several weeks of stopping treatment with Rulide D:

- * severe stomach cramps, diarrhoea with or without fever.

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

Storage

Keep the tablets in the foil until it is time to take them.

Keep the tablets/in a cool dry place where the temperature stays below 30 degrees C.

Do not store Rulide D or any other medicine in the bathroom or near a sink.

Do not leave it in the car on hot days 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 or pharmacist tells you to stop giving Rulide D to your child, 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 D are round, off-white, scored tablets. Each foil strip contains 10 tablets.

Ingredients

Active Ingredients

Each Rulide D tablets contains 50 mg of the active ingredient roxithromycin.

Inactive ingredients

Each tablet also contains:

- * cellulose - microcrystalline
- * fumaric acid
- * methacrylic acid copolymer type c
- * crospovidone
- * macrogol 6000
- * talc - purified
- * saccharin sodium
- * silica - colloidal anhydrous

- * magnesium stearate
- * triethyl citrate
- * sodium lauryl sulfate
- * sodium hydroxide
- * strawberry flavour
- * liquorice flavour

Manufacturer/Supplier

sanofi-aventis australia Pty Ltd
12-24 Talavera Road
Macquarie Park NSW 2113

Rulide D is supplied in New Zealand by:

sanofi-aventis new zealand limited
Level 8,
56 Cawley Street
Ellerslie
Auckland

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