

# Rulide® D Tablets

## Consumer Medicine Information (CMI) summary

The [full CMI](#) on the next page has more details. If you are worried about using this medicine, speak to your doctor or pharmacist.

### 1. Why am I using Rulide D?

Rulide D contains the active ingredient roxithromycin. Rulide D is mainly used to treat respiratory tract infections, and skin and soft tissue infections. For more information, see Section [1. Why am I using Rulide D?](#) in the full CMI.

### 2. What should I know before I use Rulide D?

Do not use if you have ever had an allergic reaction to roxithromycin or any of the ingredients listed at the end of the CMI.

Talk to your doctor if you have any other medical conditions, take any other medicines, or are pregnant or plan to become pregnant or are breastfeeding. For more information, see Section [2. What should I know before I use Rulide D?](#) in the full CMI.

### 3. What if I am taking other medicines?

Some medicines may interfere with Rulide D and affect how it works. A list of these medicines is in Section [3. What if I am taking other medicines?](#) in the full CMI.

### 4. How do I use Rulide D?

- For children weighing less than 40 kg, the dosage can range from one 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

More instructions can be found in Section [4. How do I use Rulide D?](#) in the full CMI.

### 5. What should I know while using Rulide D?

<b>Things you should do</b>	<ul style="list-style-type: none"><li>• Remind any doctor or dentist you visit that your child is taking Rulide D.</li><li>• If symptoms of your child's infection do not improve with a few days, or if they become worse, tell your doctor.</li><li>• If your child is about to start taking any new medicine, tell your doctor or pharmacist that they are taking Rulide D</li></ul>
<b>Things you should not do</b>	<ul style="list-style-type: none"><li>• Rulide D has been prescribed for your child. Do not give to anyone else, even if they have the same condition as your child.</li><li>• Do not use Rulide D to treat any other complaints unless your doctor tells you to</li></ul>
<b>Looking after your medicine</b>	<ul style="list-style-type: none"><li>• Keep the tablets in a cool dry place where the temperature stays below 30°C</li><li>• Keep the tablets in the foil until its time to take them</li></ul>

For more information, see Section [5. What should I know while using Rulide D?](#) in the full CMI.

### 6. Are there any side effects?

Common side effects include: rash; loss of appetite. Refer to the CMI for all side effects. For more information, including what to do if you have any side effects, see Section [6. Are there any side effects?](#) in the full CMI.

# Rulide® D Tablets (roo-ried)

Active ingredient: *Roxithromycin* (rocks-e-throw-my-sin)

## Consumer Medicine Information (CMI)

This leaflet provides important information about using Rulide D. **You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about using Rulide D.**

Where to find information in this leaflet:

- [1. Why am I using Rulide D?](#)
- [2. What should I know before I use Rulide D?](#)
- [3. What if I am taking other medicines?](#)
- [4. How do I use Rulide D?](#)
- [5. What should I know while using Rulide D?](#)
- [6. Are there any side effects?](#)
- [7. Product details](#)

## 1. Why am I using Rulide D?

**Rulide D contains the active ingredient roxithromycin.** 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 the infection.

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

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

## 2. What should I know before I use Rulide D?

### Warnings

**Do not use Rulide D if:**

- your child has an allergy to roxithromycin, or any other macrolide antibiotic e.g. azithromycin, clarithromycin or erythromycin, any of the ingredients listed at the end of this leaflet. 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.  
Always check the ingredients to make sure you can use this medicine.
- your child has severe liver problems
- your child is taking certain medicines migraine headache called ergot alkaloids e.g. Cafergot, Dihydergot; (not all brands listed)
- the product has expired or the packaging appears tampered with.

**Check with your doctor if your child:**

- have allergies to any other substances, such as foods, preservatives or dyes
- has or has had the following medical conditions:
  - kidney problems (impaired function)
  - liver problems (hepatic cirrhosis with jaundice and /or ascites)
- has any other medical conditions
- takes any medicines for any other condition

- plans to have surgery

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them. See additional information under Section [6. Are there any side effects?](#)

## 3. What if I am taking other medicines?

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

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

- theophylline (Neulin), a medicine used to treat asthma
- some medicines for migraine headache such as ergotamine (Cafergot) or dihydroergotamine (Dihydergot tablets)
- terfenadine, over the counter medicine used to treat allergies
- warfarin (Coumadin, Marevan), a medicine used to prevent blood clots
- digoxin (Lanoxin, Sigmamaxin), 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

**Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements your child is taking and if these affect Rulide D.**

## 4. How do I use Rulide D?

### How much to take

- For children weighing less than 40 kg, the dosage can range from one 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

### When to take Rulide

- 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

### 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

- 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. 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

#### How long to take it

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

Rulide D should be used regularly at the same time each day.

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

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

#### If you use too much Rulide D

If you think that your child may have used too much Rulide, your child may need urgent medical attention.

#### You should immediately:

- phone the Poisons Information Centre (**by calling 13 11 26**), or the National Poisons Centre, **0800 POISON** or **0800 764 766** (New Zealand).
- contact your doctor, or
- go to the Emergency Department at your nearest hospital.

**You should do this even if there are no signs of discomfort or poisoning.**

## 5. What should I know while using Rulide D?

#### Things you should 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 should 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

#### Looking after your medicine

- Keep the tablets in a cool dry place where the temperature stays below 30°C
- Keep your tablets in the foil until it is time to take them

Follow the instructions in the carton on how to take care of your medicine properly.

Store it in a cool dry place away from moisture, heat or sunlight; for example, do not store it:

- in the bathroom or near a sink, or
- in the car or on window sills.

Do not use this medicine after the expiry date.

**Keep it where young children cannot reach it.**

#### Getting rid of any unwanted medicine

If you no longer need to use this medicine or it is out of date, take it to any pharmacy for safe disposal.

## 6. Are there any side effects?

All medicines can have side effects. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention.

See the information below and, if you need to, ask your doctor or pharmacist if you have any further questions about 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

#### Less serious side effects

Less serious side effects	What to do
<ul style="list-style-type: none"> <li>• oral thrush - white, furry, sore tongue and mouth</li> <li>• vaginal thrush - sore and itch vagina and/or discharge</li> <li>• nausea, vomiting, stomach pain, indigestion, diarrhoea, loss of appetite, flatulence</li> <li>• rash</li> <li>• red and/or itchy skin</li> <li>• headache, dizziness, ringing in the ears</li> <li>• hallucinations</li> <li>• confusion</li> <li>• tiredness</li> <li>• altered taste</li> <li>• blurred vision and/or visual impairment</li> </ul>	<p><b>Speak to your doctor if you have any of these less serious side effects and they worry you.</b></p>

#### Serious side effects

Serious side effects	What to do
<ul style="list-style-type: none"> <li>• frequent infections such as fever, severe chills, sore throat or mouth ulcers</li> <li>• severe persistent diarrhoea</li> <li>• an allergic reaction (for example, itchy skin, rash, swelling, asthma or wheezing)</li> <li>• swelling of the face lips mouth and tongue which may cause difficulty in swallowing or breathing</li> </ul>	<p><b>Tell your doctor or pharmacist immediately or go to the Accident and Emergency Department at your nearest hospital.</b></p>

Serious side effects	What to do
<ul style="list-style-type: none"> <li>Severe blisters and bleeding in the lips, eyes, mouth, nose and genitals</li> <li>severe skin rash</li> </ul>	<p><b>These may be serious side effects or signs of a serious allergic reaction</b></p>
<ul style="list-style-type: none"> <li>severe abdominal cramps or stomach cramps</li> <li>watery and severe diarrhoea, which may sometimes be bloody</li> <li>fever, in combination with one or both of the above</li> <li></li> </ul>	<p><b>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.</b></p> <p><b>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</b></p>

(inactive ingredients)	
	<ul style="list-style-type: none"> <li>methacrylic acid copolymer type c</li> <li>crospovidone</li> <li>macrogol 6000</li> <li>talc - purified</li> <li>saccharin sodium</li> <li>silica - colloidal anhydrous</li> <li>magnesium stearate</li> <li>triethyl citrate</li> <li>sodium lauryl sulfate</li> <li>sodium hydroxide</li> <li>Strawberry Flavour Dry 995/2L 1/1000 Essepil (PI 2338)</li> <li>Liquorice Flavour Atomized (PI 2341)</li> </ul>

**Do not take this medicine if your child is allergic to any of these ingredients.**

#### What Rulide D looks like

Rulide D tablets are round, off-white, scored tablets. Each blister pack contains 10 tablets (Aust R 54811).

#### Who distributes Rulide D

Rulide D tablets are manufactured for:

sanofi aventis australia pty ltd

12-24 Talavera Road

Macquarie Park NSW 2113

This leaflet was prepared in September 2020.

rulide-d-ccds7-cmiv10-23sep20

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

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

Other side effects not listed here may occur in some people.

#### Reporting side effects

After you have received medical advice for any side effects you experience, you can report side effects to the Therapeutic Goods Administration online at [www.tga.gov.au/reporting-problems](http://www.tga.gov.au/reporting-problems) or mdsafe at <https://nzphvc.otago.ac.nz/reporting/> (New Zealand).

By reporting side effects, you can help provide more information on the safety of this medicine.

**Always make sure you speak to your doctor or pharmacist before you decide to stop taking any of your medicines.**

## 7. Product details

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

#### What Rulide D contains

<b>Active ingredient (main ingredient)</b>	Each tablet contains either 50 mg of roxithromycin
<b>Other ingredients</b>	<ul style="list-style-type: none"> <li>cellulose - microcrystalline</li> <li>fumaric acid</li> </ul>