

# Riamet® Tablets

20 mg/120 mg

Artemether and lumefantrine

## 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 Riamet Tablets?

Riamet Tablets contain the active ingredient Artemether and lumefantrine. Riamet Tablets are used to treat sudden, uncomplicated malaria caused due to a parasite called Plasmodium falciparum. It is used in adults, adolescents, and children weighing  $\geq 35$  kg or  $> 12$  years of age.

For more information, see Section [1. Why am I using Riamet Tablets?](#) in the full CMI.

### 2. What should I know before I use Riamet Tablets?

Do not use if you have ever had an allergic reaction to Riamet Tablets 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 Riamet Tablets?](#) in the full CMI.

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

Some medicines may interfere with Riamet 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 Riamet Tablets?

- Your doctor will advise you the appropriate dose.
- Follow the instructions provided when Riamet Tablets were prescribed, including the number of days it should be taken.

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

### 5. What should I know while using Riamet Tablets?

Things you should do	<ul style="list-style-type: none"><li>• Remind any doctor, dentist or pharmacist you visit that you are taking Riamet Tablets.</li><li>• Tell your doctor immediately if you become pregnant or intend to become pregnant or if you are breastfeeding.</li></ul>
Things you should not do	<ul style="list-style-type: none"><li>• Do not stop using this medicine suddenly.</li><li>• Do not use Riamet Tablets for treatment of any other types of Malaria or as a preventive measure.</li><li>• Do not give Riamet Tablets to anyone else, even if they seem to have the same condition as you</li></ul>
Driving or using machines	<ul style="list-style-type: none"><li>• Riamet Tablets may cause dizziness or unusual weakness in some people.</li><li>• If you have the above symptoms, do not drive or use machines.</li></ul>
Looking after your medicine	<ul style="list-style-type: none"><li>• Store below 30°C.</li><li>• Keep it where young children cannot reach it.</li></ul>

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

### 6. Are there any side effects?

Common side effects include numbness, headache, feeling sick, vomiting, dizziness, itching, tiredness, hives, indigestion, joint pain.

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.

# Riamet® Tablets

20 mg/120 mg

**Active ingredients:** *Artemether and lumefantrine*

## Consumer Medicine Information (CMI)

This leaflet provides important information about using Riamet Tablets. **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 Riamet Tablets.**

**Where to find information in this leaflet:**

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

## 1. Why am I using Riamet Tablets?

Riamet Tablets contains the active ingredients **Artemether and lumefantrine**. They are antimalarial medicines.

Riamet Tablets are used to treat sudden, uncomplicated malaria caused due to a parasite called *Plasmodium falciparum*. It is used in adults, adolescents, and children weighing  $\geq 35$  kg or  $> 12$  years of age. Malaria is an infectious disease which is spread by an infected *Anopheles* mosquito. The infection is caused by a parasite, and the mosquito carries the parasite and injects them into the bloodstream when it bites a person. Common symptoms include fever, chills, headache, feeling sick. Riamet Tablets help to kill the *Plasmodium falciparum* parasite.

## 2. What should I know before I use Riamet Tablets?

### Warnings

#### Do not use Riamet Tablets:

- If you are allergic to Artemether and lumefantrine, or any of the ingredients listed at the end of this leaflet. Always check the ingredients to make sure you can use this medicine. Symptoms of an allergic reaction may include shortness of breath, difficulty breathing, swelling of the face, lips, tongue or other parts of the body, rash, hives.
- In patients with severe malaria according to the World Health Organisation definition (shown by both clinical signs and blood tests).
- If you suffer from any heart diseases or any problems with your heart function.

- If you have a family history of heart rate problems, or sudden death.
- If you have symptoms such as muscle weakness, constipation, extreme tiredness (may indicate low potassium level) or weakness, cramps, or tremors (may indicate low level of magnesium in blood).

#### Check with your doctor if you:

- have any other medical conditions
- have liver or kidney problems
- take any medicines for any other condition
- suffer from heart problems, any history of heart attack, problems with heart function.

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?](#)

### Pregnancy and breastfeeding

Check with your doctor if you are pregnant or intend to become pregnant.

Do not take Riamet Tablets if you are pregnant, think you are pregnant, or intend to become pregnant.

Do not use Riamet Tablets during the first trimester of pregnancy.

Do not use Riamet Tablets in the later stages of pregnancy unless clearly indicated by your doctor. Your doctor will discuss with you the potential risks and benefits of taking Riamet Tablets during pregnancy.

Before you take Riamet Tablets, use effective contraception measures to prevent pregnancy and use it until the start of the next menstruation (period) after treatment.

If you are taking hormonal birth control medicine, transdermal patch, you should also use an additional method of birth control.

Talk to your doctor if you are breastfeeding or intend to breastfeed.

Do not take Riamet tablets during breast-feeding. It is recommended not to resume breastfeeding until at least four weeks after the last dose.

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

Tell your doctor or pharmacist if you are 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 interfere with Riamet Tablets and affect how it works.**

Tell your doctor if you use any of the following medicines:

- Any other antimalarial medicines e.g. mefloquine or quinine, halofantrine
- Anti-retroviral medicines or protease inhibitors which are used to treat HIV infections or AIDS

**Do not use Riamet Tablets if you are taking any of the following medicines:**

- medicines which are used to treat abnormal heartbeat problems (e.g. flecainide, metoprolol)
- medicines used to treat depression or other mental illnesses (e.g. imipramine, amitriptyline, clomipramine)
- rifampicin, antibiotic used to treat leprosy or tuberculosis
- medicines used to treat epilepsy (e.g. carbamazepine, phenytoin)
- St John's wort (*Hypericum perforatum*), a medicinal plant extract used to relieve some temporary feelings of sadness or low mood.
- triazole antifungal medicines (e.g. fluconazole, itraconazole)
- antibiotics (e.g. macrolides, fluoroquinolones, and imidazole)
- medicine used to treat tummy problems e.g. cisapride,
- certain medicines used to treat swelling or allergies (e.g. non-sedating antihistaminics such as terfenadine or astemizole)

**Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect Riamet Tablets.**

## 4. How do I use Riamet Tablets?

### How much to take

- Your doctor will advise you the appropriate dose.
- Follow the instructions provided when Riamet Tablets were prescribed, including the number of days it should be taken.

**Dose for adults, adolescents, and children weighing  $\geq$  35 kg or  $>$  12 years of age:**

- Take 6 doses of Riamet Tablets over a period of 3 days.
- Each of the 6 doses consists of four tablets (i.e. a total of 24 tablets are taken over 3 days).
- **Do not exceed the dose advised by your doctor.**

### When to take Riamet Tablets

- Follow the instructions provided by your doctor carefully.
- Take the first dose (4 tablets) as advised by your doctor and as soon as possible, after your doctor has diagnosed malaria.
- Take the second dose (4 tablets) 8 hours after the first dose.
- Take the third dose (4 tablets) 24 hours (exactly one day) after the first dose.
- Take the fourth dose (4 tablets) 36 hours after the first dose.

- Take the fifth dose (4 tablets) 48 hours (exactly 2 days) after the first dose.
- Take the sixth dose (4 tablets) 60 hours after the first dose.
- Do not miss any doses.

### How to take Riamet Tablets

- Swallow the tablets whole with a full glass of water or with drinks rich in fat (e.g. milk).
- Do not break the tablets.
- Whenever possible, the dose should be taken immediately after food.
- If you are feeling too unwell to eat, still take the tablets.
- Sometimes patients with malaria do not feel like eating, but you should try to eat normally as soon as you can tolerate the food, since this improves the absorption of Riamet Tablets.
- If you vomit within 1 hour of taking Riamet Tablets, take a repeat dose.

### If you forget to use Riamet Tablets

Take Riamet Tablets as prescribed by your doctor. If you miss your dose at the usual time, take the missed dose as soon as you remember, and then go back to the schedule prescribed by your doctor.

**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 many Riamet Tablets

If you think that you have used too many Riamet Tablets, you may need urgent medical attention.

**You should immediately:**

- phone the Poisons Information Centre (**by calling 13 11 26**), or
- 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 Riamet Tablets?

### Things you should do

- Do not use Riamet Tablets for treatment of any other types of Malaria or as a preventive measure.
- Riamet Tablets may reduce the effectiveness of hormonal contraceptives. If you are taking hormonal birth control medicine, transdermal patch or other systemic hormonal contraceptives, you should also use an additional method of birth control.

**Call your doctor straight away if you:**

- become pregnant or intend to become pregnant or if you are breastfeeding.

- develop any signs of an allergic reaction.
- suffer from any heart problems.
- take any other antimalarial medicines.

Remind any doctor, dentist or pharmacist you visit that you are using Riamet Tablets.

### Things you should not do

- Do not stop using this medicine suddenly.
- Do not give Riamet Tablets to anyone else, even if they seem to have the same condition as you.
- Avoid grapefruit juice during treatment with Riamet Tablets
- **Laboratory tests:**
- Your doctor may do a blood checkup e.g. monitoring blood potassium level or suggest an ECG during treatment with Riamet Tablets.

### Driving or using machines

**Be careful before you drive or use any machines or tools until you know how Riamet Tablets affect you.**

Riamet Tablets may cause dizziness or unusual weakness in some people. In such cases, do not drive or use machines.

### Looking after your medicine

- Store below 30°C.
- Keep your medicine in the original blister pack until it is time to take a dose.

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.

**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.

Do not use this medicine after the expiry date.

## 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.

### Less serious side effects

Less serious side effects	What to do
<b>General problems:</b> <ul style="list-style-type: none"> <li>• Tingling or numbness of the hands or feet</li> </ul>	<b>Speak to your doctor if you have any of these less serious side</b>

Less serious side effects	What to do
<ul style="list-style-type: none"> <li>• Sensation of pins and needles on body</li> <li>• Sleep problems</li> <li>• Headache</li> <li>• Dizziness</li> <li>• Abscess</li> <li>• Muscle pain or weakness not caused by exercise</li> <li>• Joint pain</li> <li>• Back pain</li> <li>• Itching</li> <li>• Rash</li> <li>• Fever</li> <li>• Unusual weakness</li> <li>• Tiredness</li> <li>• Shivering</li> <li>• Hives</li> <li>• Sleepiness</li> </ul>	<b>effects and they worry you.</b>
<b>Stomach problems:</b> <ul style="list-style-type: none"> <li>• Stomach pain</li> <li>• Feeling sick</li> <li>• Vomiting</li> <li>• Indigestion</li> <li>• Diarrhoea</li> <li>• Loss of appetite</li> <li>• Decreased appetite</li> </ul>	
<b>Respiratory problems:</b> <ul style="list-style-type: none"> <li>• Sore throat and discomfort when swallowing</li> <li>• Coughing</li> <li>• Fever, fatigue, skin rash, stomach problems may indicate parasitic infection</li> <li>• Fever, pain, cough, feeling sick may indicate viral infection</li> </ul>	

### Serious side effects

Serious side effects	What to do
<b>General problems:</b> <ul style="list-style-type: none"> <li>• Fever, weakness, abnormal paleness, dizziness, confusion</li> <li>• Feeling sick, vomiting, loss of appetite, feeling generally unwell, fever, itching, yellowing of the skin and eyes, light-coloured stools</li> <li>• Yellowing of the skin and/or eyes, fever, chills, dark-colored urine</li> <li>• Severe headache, dizziness, vision problems</li> </ul>	<b>Call your doctor straight away or go straight to the Emergency Department at your nearest hospital if you notice any of these serious side effects.</b>

Serious side effects	What to do
<b>Abnormal blood tests:</b> <ul style="list-style-type: none"> <li>Excessive bleeding or bruising</li> <li>Stomach pain, itching, yellowing of skin or eyes, light-coloured stools, feeling sick and vomiting</li> </ul> <b>Heart problems:</b> <ul style="list-style-type: none"> <li>Fast or irregular heart beats</li> <li>Heart rhythm problems, symptoms may include dizziness, fainting, seizure, abnormal heartbeat</li> </ul> <b>Other problems:</b> <ul style="list-style-type: none"> <li>Red/brown coloured urine, fatigue, pain in stomach</li> <li>Abnormal colour of urine</li> </ul> <b>Nervous system problems:</b> <ul style="list-style-type: none"> <li>Clumsiness and lack of coordination affecting balance and manner of walking or eye movements and/or speech</li> <li>Change in walking pattern</li> <li>Muscle spasms, pulsing, tightness, and pain</li> </ul>	

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

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). 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 Riamet Tablets contain

<b>Active ingredient (main ingredient)</b>	Artemether and lumefantrine
<b>Other ingredients (inactive ingredients)</b>	Microcrystalline cellulose, croscarmellose sodium, magnesium stearate, hypromellose, colloidal

	anhydrous silica and polysorbate 80.
<b>Potential allergens</b>	Sugars and latex (in trace amounts)

**Do not take this medicine if you are allergic to any of these ingredients.**

### What Riamet Tablets look like

Riamet Tablets (20 mg/120 mg) are pale yellow, flat, round, uncoated tablets with bevelled edges; marked with N/C and a score line on one side and CG on the other. They are available in blister packs containing 16\*, 24, or 400\* tablets.

\*Not all presentations may be available.

### Australian Registration Number:

Riamet tablet: AUST R 90011

### Who distributes Riamet Tablets

#### Riamet tablets are supplied in Australia by:

NOVARTIS Pharmaceuticals Australia Pty Limited

ABN 18 004 244 160

54 Waterloo Road

Macquarie Park NSW 2113

Telephone: 1 800 671 203

Web site: [www.novartis.com.au](http://www.novartis.com.au)

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