

Riamet® Dispersible 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 giving Riamet Dispersible Tablets to my child?

Riamet Dispersible Tablets contain the active ingredient Artemether and lumefantrine. Riamet Dispersible Tablets are used to treat sudden, uncomplicated malaria caused due to a parasite called Plasmodium falciparum. It is used in children and infants weighing between 5kg and less than 35kg and aged between ≥ 3 months up to 12 years.

For more information, see Section [1. Why am I giving Riamet Dispersible Tablets to my child?](#) in the full CMI.

2. What should I know before I give Riamet Dispersible Tablets to my child?

Do not use if your child has ever had an allergic reaction to Riamet Dispersible Tablets or any of the ingredients listed at the end of the CMI.

Talk to your doctor if your child has any other medical conditions, takes any other medicines, or is pregnant or breastfeeding.

For more information, see Section [2. What should I know before I give Riamet Dispersible Tablets to my child?](#) in the full CMI.

3. What if my child is taking other medicines?

Some medicines may interfere with Riamet Dispersible Tablets and affect how it works.

A list of these medicines is in Section [3. What if my child is taking other medicines?](#) in the full CMI.

4. How do I give Riamet Dispersible Tablets to my child?

- Your doctor will advise your child of the appropriate dose.

- Follow the instructions provided when Riamet Dispersible Tablets were prescribed, including the number of days it should be taken.

More instructions can be found in Section [4. How do I give Riamet Dispersible Tablets to my child?](#) in the full CMI.

5. What should I know while giving Riamet Dispersible Tablets?

Things you should do	<ul style="list-style-type: none"> • Remind any doctor, dentist or pharmacist you visit that your child is using Riamet Dispersible Tablets. • Tell your doctor immediately if you notice any signs of an allergic reaction in your child.
Things you should not do	<ul style="list-style-type: none"> • Do not stop giving this medicine suddenly to your child. • Do not exceed the dose advised by your doctor. • Do not let your child do anything that could be dangerous, as Riamet Dispersible Tablets may cause dizziness or

	unusual weakness in some children.
Looking after the medicine	<ul style="list-style-type: none"> • Store below 30°C. • Protect from moisture.

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

6. Are there any side effects?

Common side effects include headache, feeling sick, vomiting, dizziness, itching, decreased appetite, tiredness, hives.

For more information, including what to do if your child has any side effects, see Section [6. Are there any side effects?](#) in the full CMI.

Riamet® Dispersible Tablets

Active ingredients: *Artemether and lumefantrine*

Consumer Medicine Information (CMI)

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

Where to find information in this leaflet:

- [1. Why am I giving Riamet Dispersible Tablets to my child?](#)
- [2. What should I know before I give Riamet Dispersible Tablets to my child?](#)
- [3. What if my child is taking other medicines?](#)
- [4. How do I give Riamet Dispersible Tablets to my child?](#)
- [5. What should I know while giving Riamet Dispersible Tablets?](#)
- [6. Are there any side effects?](#)
- [7. Product details](#)

1. Why am I giving Riamet Dispersible Tablets to my child?

Riamet Dispersible Tablets contain the active ingredients Artemether and lumefantrine. They are antimalarial medicines.

Riamet Dispersible Tablets are used to treat sudden, uncomplicated malaria caused by a parasite called *Plasmodium falciparum*. It is used in children and infants weighing between 5kg and less than 35kg and between aged ≥ 3 months up to 12 years.

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 Dispersible Tablets help to kill the *Plasmodium falciparum* parasite.

2. What should I know before I give Riamet Dispersible Tablets to my child?

Warnings

Do not use Riamet Dispersible Tablets:

- If your child is 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.
- If your child suffers from severe malaria (e.g. affecting your child's brain, kidneys, or lungs) according to the

World Health Organization definition (shown by both clinical signs and blood tests).

- If they have any heart diseases or any problems with heart function, heart rate problems.
- If they 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 your child:

- has any other medical conditions, any liver or kidney problems.
- takes any medicines for any other condition
- has any heart problems, severe heart disease, heart rhythm problems, any family history of heart problems.
- suffers from liver or kidney problems.

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 your child is pregnant.

Do not give Riamet Dispersible Tablets to your child if you think she is pregnant or if she becomes pregnant while taking Riamet Dispersible Tablets.

Do not give Riamet Dispersible Tablets to your child during the first trimester of pregnancy.

Do not give Riamet Dispersible Tablets to your child 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 Dispersible Tablets during pregnancy.

If your daughter is taking hormonal birth control medicine, she should also use an additional method of birth control while on treatment with Riamet Dispersible Tablets

Talk to your doctor if your child is breastfeeding.

Do not give your child Riamet Dispersible Tablets while breast-feeding. It is recommended not to resume breastfeeding until at least four weeks after the last dose.

3. What if my child is taking other medicines?

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

Some medicines may interfere with Riamet Dispersible Tablets and affect how it works.

Tell your doctor if your child takes any of the following medicines:

- Any other antimalarial drugs e.g. mefloquine or quinine, halofantrine

- Anti-retroviral medicines or protease inhibitors which are used to treat HIV infections or AIDS

Do not give Riamet Dispersible Tablets to your child if they 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)
- medicines used to treat stomach 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 Dispersible Tablets.

4. How do I give Riamet Dispersible Tablets to my child?

How much to give

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

Dose for infants and children weighing 5 kg to < 35 kg, and aged \geq 3 months up to 12 years:

- The treatment consists of a total of six-doses given over a period of 60 hours (2.5 days).
- The following are the recommended doses depending on your child's body weight:
 - 5 kg to less than 15 kg: 1 tablet per dose
 - 15 kg to less than 25 kg: 2 tablets per dose
 - 25 kg to less than 35 kg: 3 tablets per dose.
- The number of tablets per dose will be the same at each time interval.
- Do not exceed the dose advised by your doctor.
- **Contact your doctor or pharmacist if you do not understand your dose.**

When to give Riamet Dispersible Tablets

- Your doctor will advise you regarding when to give Riamet Dispersible Tablets to your child

- Give your child a total of six doses (over 3 days) based on body weight as follows:

5 to < 15 kg bodyweight and \geq 3 months:

- Dose 1:
- Give 1 dispersible tablet to your child as advised by your doctor as soon as possible, after your doctor has diagnosed malaria.

Dose 2:

- Give 1 tablet after 8 hours after the first dose.

Dose 3 to 6:

- Give 1 tablet to your child twice daily (morning and evening) on each of the following two days (total course comprises 6 tablets).

15 to < 25 kg bodyweight:

- Dose 1:
- Give 2 dispersible tablets to your child as advised by your doctor as soon as possible, after your doctor has diagnosed malaria.
- Dose 2:
- Give 2 tablets again after 8 hours after the first dose.

Dose 3 to 6:

- Give 2 tablets twice daily (morning and evening) on each of the following two days (total course comprises 12 tablets).

25 to < 35 kg bodyweight & < 12 years:

- Dose 1:

- Give 3 dispersible tablets to your child as advised by your doctor as soon as possible, after your doctor has diagnosed malaria.

Dose 2:

- Give 3 tablets again after 8 hours after the first dose.

Dose 3 to 6:

- Give 3 tablets twice daily (morning and evening) on each of the following two days (total course comprises 18 tablets).

How to give Riamet Dispersible Tablets

- Before giving Riamet Dispersible tablet(s), immediately place the tablet(s) in a drinking glass or cup, containing a small amount of water (approximately 10 mL per tablet).
- Allow the tablet(s) to disintegrate, stir it gently and give it to your child to drink.
- Then, rinse the glass with an additional small amount of water (approximately 10 mL) and give it to your child to drink completely.
- The tablets should be immediately followed by food or drinks rich in fat (e.g. milk).
- If your child is too unwell to eat or drink, you should still give him/her Riamet Dispersible Tablet(s) as prescribed.
- Contact your doctor or pharmacist immediately if your child vomits within one hour of taking the dose.

If you forget to give Riamet Dispersible Tablets

Give Riamet Dispersible Tablets to your child as prescribed by your doctor. If your child missed his/her dose at the usual time, give your child the missed dose as soon as you remember, and then give the next dose at the usual time.

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

Do not give a double dose to make up for the dose your child has missed.

If you give too many Riamet Dispersible Tablets

If you think that you have given too many Riamet Dispersible Tablets to your child, your child 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 giving Riamet Dispersible Tablets?

Things you should do

- Remember to give your child all six doses at the indicated time intervals.
- **Your daughter must not breast-feed whilst taking this medicine and for 4 weeks after she has taken the last tablet.**

Call your doctor straight away:

- If you notice any signs of an allergic reaction in your child
- If your child is too unwell to eat or drink or if the condition worsens.
- If your child keeps vomiting.

Remind any doctor, dentist or pharmacist you visit that your child is using Riamet Dispersible Tablets.

Things you should not do

- Do not suddenly stop giving this medicine to your child.
- Do not give Riamet Dispersible Tablets to anyone else, even if they seem to have the same condition as your child.
- Avoid giving grapefruit juice to your child during treatment.

- Do not exceed the dose advised by your doctor.
- Do not let your child do anything that could be dangerous, as Riamet Dispersible Tablets may cause dizziness or unusual weakness in some children.

Laboratory tests:

- Your doctor may advise you to take your child for a blood checkup e.g. monitoring blood potassium level or suggest an ECG during treatment with Riamet Dispersible Tablets

Driving or using machines

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

Looking after the medicine

- Store below 30°C.
- Protect from moisture

Follow the instructions in the carton on how to take care of your child's 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 give this medicine or it is out of date, take it to any pharmacy for safe disposal.

Do not give this medicine after the expiry date.

6. Are there any side effects?

All medicines can have side effects. If your child does 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
General problems: <ul style="list-style-type: none">• Headache• Dizziness• Sleepiness• Cough• Rash• Hives• Itching• Joint pain	Speak to your doctor if your child has any of these less serious side effects and they worry you.

Less serious side effects	What to do
<ul style="list-style-type: none"> • Muscle pain or weakness not caused by exercise • Tiredness • Unusual weakness <p>Stomach problems:</p> <ul style="list-style-type: none"> • Decreased appetite • Loss of appetite • Vomiting • Pain in stomach • Diarrhoea • Feeling sick 	

Serious side effects

Serious side effects	What to do
<p>Abnormal lab tests:</p> <ul style="list-style-type: none"> • Stomach pain, itching, yellowing of your child's skin or eyes, light-colored stools, feeling sick, vomiting • Fevers, chills, body aches, sore throat, coughing 	<p>Call your doctor straight away or go straight to the Emergency Department at your nearest hospital if your child has any of these serious side effects.</p>

Serious side effects	What to do
<ul style="list-style-type: none"> • Excessive bleeding or bruising • Weakness, pale skin, dizziness, shortness of breath <p>Heart problems:</p> <ul style="list-style-type: none"> • Fast or irregular heart beats <p>Other Problems:</p> <ul style="list-style-type: none"> • Involuntary muscle contractions, twisting or repetitive movements or abnormal postures. <p>Stomach problems:</p> <ul style="list-style-type: none"> • Fever, fatigue, rash, weight loss, yellowing of your child's skin or eyes. • 	

Tell your doctor or pharmacist if you notice anything in your child that makes him/her feel unwell.

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

Reporting side effects

After your child has received medical advice for any side effects they experience, you can report side effects to the Therapeutic Goods Administration online at 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 giving any of your child's medicine.

7. Product details

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

What Riamet Dispersible Tablets contain

Active ingredient (main ingredient)	Artemether and lumefantrine
Other ingredients (inactive ingredients)	Microcrystalline cellulose, croscarmellose sodium, magnesium stearate, hypromellose, colloidal anhydrous silica and polysorbate 80, sodium saccharin and cherry flavour

Potential allergens	Sugars and latex (in trace amounts)
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Do not give this medicine if your child is allergic to any of these ingredients.

What Riamet Dispersible Tablets look like

Riamet Dispersible Tablets (20 mg/120 mg) are flat, yellow, round, uncoated tablets with bevelled edges; imprinted with “CD” on one side and “NVR” on the other side. Blister packs containing 6*, 12*, 18, 180*, 360*, 540* dispersible tablets.

*Not all presentations may be available.

Australian Registration Number:

Riamet 20 mg/120 mg Dispersible tablets: AUST R 158523

Who distributes Riamet Dispersible Tablets

Riamet Dispersible tablets are supplied in Australia by:

NOVARTIS Pharmaceuticals Australia Pty Limited

ABN 18 004 244 160

54 Waterloo Road

Macquarie Park NSW 2113

Telephone: 1800 671 203

Web site: www.novartis.com.au

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