
Information for patients

Read this leaflet carefully before taking/using this medicine. This medicine has been prescribed for you personally. Do not pass it on to anyone else. It may harm them even if their symptoms are the same as yours.

Keep this leaflet. You may want to read it again later.

Riamet® Dispersible

Riamet® Baby

What Riamet Dispersible and Riamet Baby are and what they are used for

Riamet Dispersible and Riamet Baby are used to treat acute, uncomplicated malaria caused by *Plasmodium falciparum* (a particular type of malaria pathogen). Riamet Dispersible and Riamet Baby contain the 2 active substances artemether and lumefantrine. They work by killing the malaria pathogen.

Infection with malaria occurs when Anopheles mosquitoes transmit malaria pathogens (plasmodia) to humans through their bite. Symptoms of malaria can occur 1 week after the mosquito bite at the earliest (see “How to use Riamet Dispersible and Riamet Baby”).

Riamet Dispersible is used to treat infants and children weighing at least 5 kg to less than 35 kg and aged up to 12 years. Riamet Dispersible is not recommended for use in infants weighing under 5 kg.

Riamet Dispersible can also be prescribed to people travelling to a malaria area as a medicine for standby emergency treatment, e.g. for journeys to remote regions where it might not be possible to get quick medical help. In such cases, the prescribing doctor can prescribe Riamet Dispersible so that you as a parent or caregiver can keep it with you and administer it to the travelling child (“standby emergency treatment”).

Please note that such treatment is a first aid measure, i.e. may only be given if malaria is suspected, and that medical help must still be sought as quickly as possible.

Riamet Baby is used to treat newborns and infants weighing at least 2 kg and less than 5 kg.

Riamet Baby is not suitable for use in infants or children weighing 5 kg or more.

Riamet Dispersible and Riamet Baby are not used to prevent malaria or treat severe malaria (where the brain, lungs or kidneys are affected).

Riamet Dispersible and Riamet Baby must only be taken if prescribed by a doctor.

Additional information to be aware of

As a treatment, Riamet Dispersible and Riamet Baby cannot replace the following protective measures. Protect your child from mosquito bites. Anopheles mosquitoes mainly bite from dusk to dawn.

During this period, it is therefore recommended to:

- Use mosquito repellent
- Wear clothes that cover the skin as much as possible
- Use a mosquito net at night in bedrooms that are not protected from mosquitoes.

Please note that Riamet Dispersible and Riamet Baby cannot be used indiscriminately against all malaria pathogens in every region. To avoid complications that can be caused by taking the wrong malaria medicine or the wrong dose of malaria medicine, do not give your child Riamet Dispersible (also during later journeys to a malaria area) and Riamet Baby without consulting a doctor or pharmacist.

Do not give Riamet Dispersible and Riamet Baby

- Do not give Riamet Dispersible and Riamet Baby if your child is allergic to any of the active substances or other ingredients contained in this medicine. If you think your child may be allergic, ask your child's doctor for advice.
- If your child is taking other medicines to treat malaria containing the active substance halofantrine or quinine.
- If your child has severe liver or kidney problems.
- In the event of severe malaria affecting the brain, lungs or kidneys.
- If your child has a heart condition such as a heart rhythm disorder, slow heartbeat, severe heart disease or, for example, an abnormal electrical signal showing on their ECG called "prolongation of the QT interval".
- If a member of your child's family (e.g. parents, grandparents, brothers and sisters) has died suddenly due to a heart problem or has had problems with their heart rate since birth.
- If the concentrations of electrolytes such as potassium or magnesium in your child's blood are low.
- In the event of severe dehydration or problems eating. If this is the case, you must go to the nearest hospital.
- If your child is taking certain medicines:
 - Medicines to treat heart rhythm disorders (antiarrhythmics), e.g. flecainide, metoprolol
 - Medicines to treat high blood pressure (beta blockers)
 - Medicines to treat depression (neuroleptics, antidepressants) such as imipramine, amitriptyline, clomipramine
 - Certain antibiotics and medicines to treat fungal infections (e.g. rifampicin, an antibiotic to treat leprosy or tuberculosis, macrolides, fluoroquinolones, imidazoles, triazoles)

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- Non-drowsy medicines to treat allergies (e.g. terfenadine, astemizole)
 - Medicines containing the active substance cisapride (e.g. Prepulsid®)
 - Certain medicines to treat epilepsy (such as carbamazepine, phenytoin)
 - St. John's wort (*Hypericum perforatum*), a plant used to treat depression.

If any of these apply to your child, do not give your child Riamet Dispersible or Riamet Baby and tell your child's doctor.

Warnings and precautions

If your child's condition worsens or if they feel too unwell to eat and drink, please contact your child's doctor immediately. Before and during treatment, your child's doctor may perform a test called an electrocardiogram (ECG) and check the concentrations of electrolytes such as potassium and magnesium in your child's blood.

If your child is taking or has taken other medicines to treat malaria, talk to the doctor about this as some of these medicines must not be given together with Riamet Dispersible or Riamet Baby.

The active substances of Riamet Dispersible/Riamet Baby may affect the effectiveness of hormonal contraceptives. If your daughter is using a hormonal contraceptive, she should also use a non-hormonal method of contraception (see also "Pregnancy and breast-feeding").

Talk to your daughter's doctor if your daughter is in the first 3 months of pregnancy or if it is possible that your daughter is pregnant. The doctor may prescribe your daughter a different medicine to treat malaria.

Also tell your child's doctor if your child is taking medicines to treat HIV infections or AIDS.

Dizziness and/or tiredness may occur after taking Riamet Dispersible and the ability to drive or operate machines may be reduced.

Riamet Dispersible and Riamet Baby contain less than 1 mmol (23 mg) of sodium per tablet, making them practically "sodium-free".

Riamet Dispersible and Riamet Baby contain ethyl benzoate and may increase jaundice (yellowing of the skin and eyes) in newborns (up to 4 weeks of age).

Also tell the doctor or pharmacist if your child:

- Has any other illnesses,
- Has any allergies,
- Is taking or externally applying any other medicines (including non-prescription medicines).

Pregnancy and breast-feeding

Riamet Dispersible should only be taken during pregnancy and breast-feeding if this has been discussed with the doctor.

Riamet Dispersible must not be used during the first 3 months of pregnancy if the doctor can prescribe your daughter a different medicine to treat malaria as this could have serious consequences for the unborn child. Your daughter should only take Riamet Dispersible later on in the pregnancy if this is clearly necessary and if the doctor considers it appropriate.

If your daughter is using hormonal contraceptives, she must use an additional, non-hormonal method of contraception. Talk to your daughter's doctor about suitable contraceptives.

If your daughter is pregnant, pregnancy is suspected or if she becomes pregnant during treatment with Riamet Dispersible, tell your daughter's doctor.

As Riamet Dispersible must not be used during the first 3 months of pregnancy, women of childbearing potential carrying Riamet Dispersible with them as an emergency medicine are advised to use an effective method of contraception for the duration of their journey, while using Riamet Dispersible and until the start of their next period after treatment.

Your daughter should not breast-feed while taking Riamet Dispersible. After Riamet Dispersible is stopped, she should not start breast-feeding again until at least 4 weeks after taking the last tablet.

Riamet Baby is not intended for use in women of childbearing age.

How to use Riamet Dispersible and Riamet Baby

Malaria caused by *Plasmodium falciparum* is a serious, life-threatening disease and must be fully treated. Therefore, it is very important that Riamet Dispersible and Riamet Baby are taken as prescribed by the doctor and that all prescribed dispersible tablets are taken, even if your child feels better after a while. If your child stops taking the dispersible tablets too soon, the symptoms may return. If your child's doctor or pharmacist has given you Riamet Dispersible before travel to a malaria area with the recommendation to take Riamet Dispersible if malaria symptoms occur (standby emergency treatment), please note the following:

Malaria must always be suspected if your child starts to experience unexplained fever with or without other signs such as headache, muscle pain, weakness, nausea, vomiting, diarrhoea, abdominal pain and cough. These symptoms may occur in the period from one week after possible initial contact with malaria (i.e. after entering a malaria area) up to 2 months after the last possible contact. In some cases, it may even take longer than 2 months. In any case, your child should consult a doctor immediately if the described symptoms occur.

Riamet Dispersible should only be used for self-treatment if a doctor cannot be reached within the next 24 hours.

Self-treatment should also only be carried out if your child has already spent at least 8 days in a region where malaria occurs.

Even if self-treatment has been carried out, you should consult a doctor as soon as possible, who can determine whether your child has malaria or another disease and may initiate further treatment measures.

How to give Riamet Dispersible and Riamet Baby to your child

Follow the doctor's instructions exactly.

Your child's doctor will tell you exactly how many Riamet Dispersible or Riamet Baby tablets to give your child. If you are unsure about how much Riamet Dispersible or Riamet Baby to give or when to give it, please ask your child's doctor or a pharmacist.

Riamet Dispersible

For infants and children weighing 5 kg to less than 35 kg and 12 years of age and less

Put Riamet Dispersible tablets in a cup with some water (approximately 10 ml per tablet). Wait until the tablet(s) has/have dissolved and stir gently before giving the liquid to your child to drink. Then refill the cup with some water (approximately 10 ml) and ensure your child drinks it all.

After the Riamet Dispersible tablets, food or drinks rich in fat (e.g. milk) should be consumed as they improve the absorption and therefore the effectiveness of Riamet Dispersible. A fat content of 30 to 60 g per day or breast milk is sufficient. If your child feels too unwell to eat or drink, you should still give them Riamet Dispersible and contact your child's doctor.

How much Riamet Dispersible to give:

The treatment consists of a total of 6 doses (1 to 3 tablets per dose) taken over 3 days according to the following table. Do not exceed the recommended dose.

The first dose is taken at the time of diagnosis or as soon as symptoms occur; the second dose is taken 8 hours later. On each of the following two days, one dose is taken twice daily (in the morning and evening, 12 hours apart). A total of 6 doses are taken over 3 days according to the following table:

Usual dosage for infants and children weighing at least 5 kg to less than 35 kg and 12 years of age or less

	Children 25-<35 kg	Children 15-<25 kg	Children 5-<15 kg
<i>1st dose: immediately</i>	3 tablets	2 tablets	1 tablet
<i>2nd dose: 8 hours later</i>	3 tablets	2 tablets	1 tablet
<i>3rd dose:</i>	3 tablets	2 tablets	1 tablet
<i>4th dose:</i>	3 tablets	2 tablets	1 tablet
<i>5th dose:</i>	3 tablets	2 tablets	1 tablet

	Children 25-<35 kg	Children 15-<25 kg	Children 5-<15 kg
<i>6th dose:</i>	3 tablets	2 tablets	1 tablet
<i>Total</i>	18 tablets	12 tablets	6 tablets

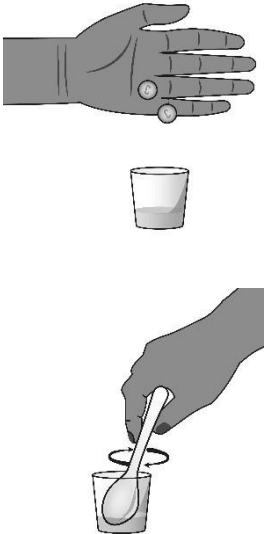

If your child vomits within the first hour of taking Riamet Dispersible tablets, give your child the prescribed number of tablets again and tell the doctor or pharmacist immediately.

Keep to the exact dosage prescribed by your child's doctor and only use the required number of Riamet Dispersible tablets.

Return any remaining tablets to a pharmacist for proper disposal.

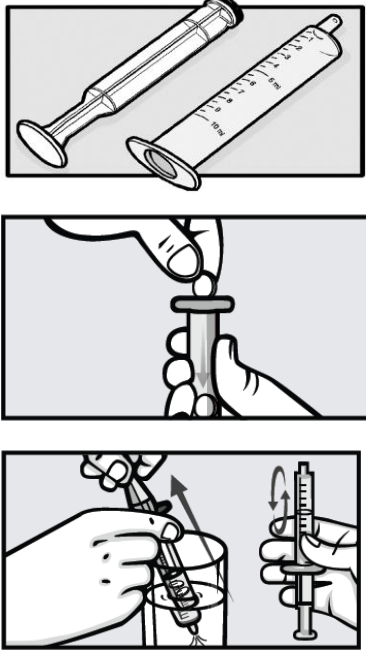

Riamet Baby

For newborns and infants weighing at least 2 kg and less than 5 kg:

	<p>Add 2 Riamet Baby dispersible tablets to a small amount of water (around one teaspoon [3 ml]) in a small drinking cup.</p> <p>Stir gently until the tablets have completely dissolved.</p>
	<p>Immediately give your child the liquid carefully from the same drinking cup. Then add about another teaspoon (3 ml) of water into the drinking cup, swirl it around and give the liquid to your child. Make sure your child drinks everything.</p> <p>After each dose, feed your child with breastmilk or formula milk, as high-fat food improves the absorption—and therefore the effectiveness—of Riamet Baby. If your child feels too unwell to eat or drink, you should still give them Riamet Baby and contact your child's doctor.</p>

or

Follow these steps if you are using an oral syringe (preferably a 5 ml syringe):

	<p>Take a clean oral syringe and remove the plunger by pulling it back. Place two Riamet Baby dispersible tablets into the oral syringe. Reinsert the plunger.</p> <p>Fill a drinking glass or cup with water and draw the water into the syringe by slowly pulling the plunger to the 3 ml mark to cover the tablets.</p> <p>Gently turn the syringe upside down a few times until the tablets have completely dissolved. DO NOT SHAKE.</p>
	<p>Immediately after preparation, slowly and carefully inject the entire contents of the oral syringe into the inside of the child's cheek.</p> <p>Then draw more water (3 ml) into the oral syringe and give the liquid to your child. Make sure your child drinks everything.</p> <p>After each dose, feed your child with breastmilk or formula milk, as high-fat food improves the absorption –and therefore the effectiveness– of Riamet Baby. If your child feels too unwell to eat or drink, you should still give them Riamet Baby and contact your child's doctor.</p>

How much Riamet Baby to give:

6 doses of 2 dispersible tablets each must be given over 3 days, as follows:

The first dose of 2 dispersible tablets is given at the time of diagnosis, the second dose of 2 dispersible tablets is given 8 hours afterwards. On each of the following two days, 2 dispersible tablets are given twice daily (at 12-hour intervals, e.g. morning and evening).

To fully treat your child's malaria, it is very important that all 12 dispersible tablets are taken over the 3 days at intervals as indicated.

If your child vomits within one hour of taking the tablets, give your child another dose of 2 dispersible tablets and tell your child's doctor or pharmacist immediately.

What to do if you forget a dose

If you have forgotten to give your child a dose of Riamet Dispersible or Riamet Baby, give it to them as soon as you realise. Then give your child the next dose at the usual time. Do not give your child a double dose to make up for a forgotten dose.

What to do in the event of overdose

If you have accidentally given your child more tablets of Riamet Dispersible or Riamet Baby than prescribed by your doctor, you should immediately take your child to a doctor or the emergency department of the nearest hospital, or ensure that someone consults an emergency doctor for your child. Take the medicine or the empty package with you.

What to do if the symptoms return after treatment

If signs of malaria return after treatment with Riamet Dispersible or Riamet Baby, a doctor must always be consulted immediately. Your child's doctor will decide on further malaria treatment.

Do not change the prescribed dosage yourself. If you think the effect of the medicine is too weak or too strong, talk to your child's doctor or pharmacist.

Possible side effects

As with all medicines, Riamet Dispersible or Riamet Baby may have side effects, although not everyone gets them.

Very common (affects more than 1 in 10 users)

Loss of appetite, cough, vomiting.

Common (affects 1 to 10 in 100 users)

Headache, dizziness, stomach pain, diarrhoea, nausea, skin rash, muscle and joint pain, involuntary muscle contractions, tiredness and general exhaustion, symptoms such as unexplained, persistent nausea, stomach problems, loss of appetite or unusual tiredness or weakness (signs of liver problems), prolonged electrocardiogram QT.

Uncommon (affects 1 to 10 in 1,000 users)

Sleep disorders, drowsiness, heart palpitations, pruritus (itching).

Rare (affects 1 to 10 in 10,000 users)

Allergic reaction (e.g. rash, itching, swelling (particularly of the face or throat), breathing or swallowing difficulties or dizziness) and heart rhythm disorders (QT prolongation).

Some side effects may be serious. You should talk to your child's doctor as soon as you notice that your child is experiencing the following side effect: allergic reaction (skin rash and/or facial redness, swelling (particularly of the face or throat area), difficulty breathing or swallowing).

If your child vomits within one hour of taking the dispersible tablets, give your child the prescribed number of dispersible tablets again and tell your child's doctor or pharmacist immediately.

The other side effects mentioned generally do not require treatment; however, you should contact your child's doctor if any of them last for a long time or become particularly unpleasant.

There have been reports of the following uncommon side effects in adults, but not in infants or children: movement disorders, abnormal gait, tingling or reduced sensation.

If you notice that your child is experiencing any side effects, contact your child's doctor or pharmacist.

This also applies particularly to side effects not listed in this leaflet.

Further information

Do not use this medicine after the expiry date (= EXP) printed on the container.

Storage instructions

Riamet Dispersible and Riamet Baby

Keep out of the reach of children.

Do not store above 30°C.

Store in the original pack and protect from heat and moisture.

Additional information

Your doctor or pharmacist will be able to give you more information. They have access to the full prescribing information.

What Riamet Dispersible and Riamet Baby contain

Riamet Dispersible

1 dispersible tablet contains:

Active substances

20 mg artemether, 120 mg lumefantrine.

Other ingredients

Microcrystalline cellulose, hypromellose, colloidal anhydrous silica, polysorbate 80, croscarmellose sodium, magnesium stearate, crospovidone, saccharin sodium, cherry flavouring (contains ethyl benzoate), maltodextrin.

Riamet Baby

1 dispersible tablet contains:

Active substances

2.5 mg artemether, 30 mg lumefantrine.

Other ingredients

Microcrystalline cellulose, hypromellose, colloidal anhydrous silica, polysorbate 80, croscarmellose sodium, magnesium stearate, crospovidone, saccharin sodium, cherry flavouring (contains ethyl benzoate).

Authorisation number

58528, 67664 (Swissmedic)

Availability/Pack sizes

The product can be obtained in pharmacies with a doctor's prescription, which may be used once.

What are the contents of the pack for Riamet Dispersible?

Pack contains 12 tablets.

The child's parents or caregiver should be given the necessary information for dosing based on the child's body weight. Depending on the dose needed, it is possible that not all tablets in the pack will be used. Leftover tablets should be brought to a pharmacy for proper disposal.

What are the contents of the pack for Riamet Baby?

Each pack contains 1 blister strip with 12 dispersible tablets.

Marketing authorisation holder

Novartis Pharma Schweiz AG, Risch, Switzerland; domicile: 6343 Rotkreuz, Switzerland

This package leaflet was last reviewed by the Swiss Agency for Therapeutic Products (Swissmedic) in February 2025.