

Information for patients

Read this leaflet carefully before taking 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®

What Riamet® is and what it is used for

Riamet is used to treat acute, uncomplicated malaria caused by *Plasmodium falciparum* (a particular type of malaria pathogen). Riamet contains the 2 active substances artemether and lumefantrine. It works 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"). Riamet can be used both in adults and children with a body weight of 5 kg and above.

Riamet 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.

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

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

Riamet must only be taken if prescribed by a doctor.

Additional information to be aware of

As a standby emergency treatment, Riamet cannot replace the following protective measures. Protect yourself 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 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 take Riamet (also during later journeys to a malaria area) without consulting your doctor or pharmacist.

Do not take Riamet

Do not take Riamet:

- If you are allergic to any of the active substances or other ingredients contained in this medicine. If you think you may be allergic, ask your doctor for advice.
- If you are taking other medicines to treat malaria containing the active substance halofantrine or quinine.
- If you have a severe liver or kidney disorder.
- In the event of severe malaria affecting the brain, lungs or kidneys.
- If you have a heart condition such as a heart rhythm disorder, slow heartbeat, severe heart disease or, for example, an abnormal electrical signal showing on your ECG called “prolongation of the QT interval”.
- If a member of your family (e.g. parents, grandparents, brothers and sisters) has died suddenly due to a heart problem or has had heart problems since birth.
- If the concentrations of electrolytes such as potassium or magnesium in your 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 you are 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)
- 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.

Warnings and precautions

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

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

If you are taking or have taken other medicines to treat malaria, talk to your doctor about this as some of these medicines must not be given together with Riamet.

Riamet may affect the effectiveness of hormonal contraceptives. If you are using a hormonal contraceptive, you should therefore also use a non-hormonal method of contraception (see also "Pregnancy and breast-feeding").

Talk to your doctor if you are in the first 3 months of pregnancy or you plan to become pregnant. Your doctor may give you a different medicine to treat malaria.

Tell your doctor if you are taking medicines to treat HIV infection or AIDS.

This medicine contains less than 1 mmol (23 mg) of sodium per tablet, making it practically "sodium-free".

Also tell your doctor or pharmacist if you:

- Have any other illnesses
- Have any allergies

- Are taking or externally applying any other medicines (including non-prescription medicines).

Pregnancy and breast-feeding

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

Riamet should not be used during the first 3 months of pregnancy if your doctor can give you a different medicine to treat malaria as this could have serious consequences for your unborn child. You should only take Riamet later on in the pregnancy if this is clearly necessary.

If you are using hormonal contraceptives, you must use an additional, non-hormonal method of contraception. Talk to your doctor about suitable contraceptives.

If you are pregnant, suspect that you may be pregnant or have become pregnant during treatment with Riamet, tell your doctor.

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

You should not breast-feed while taking Riamet. After you stop taking Riamet, you should not start breast-feeding again until at least 4 weeks after taking the last tablet.

How to use Riamet®

Malaria caused by *Plasmodium falciparum* is a serious, life-threatening disease and must be fully treated. Therefore, it is very important that Riamet is taken as prescribed by your doctor and that all prescribed tablets are taken, even if you feel better after a while. If you stop taking the tablets too soon, the symptoms may return.

If your doctor or pharmacist has given you Riamet before travel to a malaria area with the recommendation to take Riamet if malaria symptoms occur (standby emergency treatment), please note the following:

Malaria must always be suspected if you start 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 you should consult a doctor immediately if the described symptoms occur.

Riamet 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 you have 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 you have malaria or another disease and may initiate further treatment measures.

Patients with acute malaria often have problems eating. However, you should ensure you eat normally as soon as possible as this improves the absorption and therefore the effectiveness of Riamet.

If you vomit within 1 hour of taking the tablets, you should take the prescribed number of tablets again.

The tablets should be taken with drinks or food containing fat, e.g. milk. A fat content of 30 to 60 g per day or breast milk is sufficient.

The treatment consists of a total of 6 doses (1 to 4 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:

	Adults + children from 35 kg or from 12 years of age	Children 25-<35 kg	Children 15-<25 kg	Children 5-<15 kg
		up to the age of 12 years		
1st dose: immediately	4 tablets	3 tablets	2 tablets	1 tablet

2nd dose: 8 hours later	4 tablets	3 tablets	2 tablets	1 tablet
3rd dose:	4 tablets	3 tablets	2 tablets	1 tablet
4th dose:	4 tablets	3 tablets	2 tablets	1 tablet
5th dose:	4 tablets	3 tablets	2 tablets	1 tablet
6th dose:	4 tablets	3 tablets	2 tablets	1 tablet
Total	24 tablets	18 tablets	12 tablets	6 tablets

For administration to infants and children the tablet(s) may be crushed just before administration; however, it must be ensured that the whole prescribed dosage is swallowed. Dispersible tablets are also available for administration to infants and children.

Keep to the exact dosage prescribed by your doctor and only use the required number of tablets.

Return any remaining tablets to a pharmacist for proper disposal.

What to do if you forget a dose

If you forget to take a dose, take it as soon as you realise. Then take the next dose at the usual time. Do not take a double dose to make up for a forgotten dose.

What to do in the event of overdose

If you have accidentally taken many more tablets than prescribed by your doctor, you should immediately consult a doctor or go to the emergency department of the nearest hospital or ensure that someone consults an emergency doctor for you. 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, a doctor must always be consulted immediately. Your doctor will decide on further malaria treatment.

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

Possible side effects

Most side effects are mild to moderate and usually disappear after a few days or weeks of treatment. Some side effects occurred more frequently in children and others more frequently in adults.

Very common (affects more than 1 in 10 users)

Loss of appetite, sleep disorders, headache, dizziness, heart palpitations, cough, stomach pain, nausea and/or vomiting, muscle and joint pain, tiredness and general exhaustion.

Common (affects 1 to 10 in 100 users)

Involuntary muscle contractions, diarrhoea, itchy skin or skin rash, 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)

Drowsiness.

The following uncommon side effects were only recorded in adults:

Decreased feeling or sensitivity (especially skin), uncoordinated movement, gait disturbance and sleeplessness.

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 doctor as soon as you notice any of the following side effects: allergic reaction (skin rash and/or facial redness, swelling (particularly of the face or throat area), difficulty breathing or swallowing).

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

If you notice any side effects, contact your doctor or pharmacist. This also applies particularly to side effects not listed in this leaflet.

Further information

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

Storage instructions

Keep out of the reach of children.

Do not store above 30°C.

Store in the original pack and protect from 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® contains

1 tablet contains:

Active substances

20 mg artemether, 120 mg lumefantrine

Other ingredients

Microcrystalline cellulose, hypromellose, colloidal anhydrous silica, polysorbate 80, croscarmellose sodium, magnesium stearate.

Swissmedic number

54594

Availability/pack sizes

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

Pack contains 24 tablets. There is no special pack for children and infants. 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.

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 December 2019.