

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® Dispersible

What Riamet® Dispersible is and what it is used for

Riamet Dispersible is used to treat acute, uncomplicated malaria caused by *Plasmodium falciparum* (a particular type of malaria pathogen). Riamet Dispersible 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 Dispersible”). Riamet Dispersible is used to treat infants and children weighing from 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 Dispersible is not used to prevent malaria or treat severe malaria (where the brain, lungs or kidneys are affected).

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

Additional information to be aware of

As a standby emergency treatment, Riamet Dispersible 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 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) without consulting a doctor or pharmacist.

Do not give Riamet® Dispersible

Do not give Riamet Dispersible:

- 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 doctor for advice.
- If your child is taking other medicines to treat malaria containing the active substance halofantrine or quinine.
- If your child has a severe liver or kidney disorder.
- 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)
- 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 Dispersible and your ability to drive or operate machines may be reduced.

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 their blood.

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

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

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

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

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

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 a doctor.

Riamet Dispersible must not be used during the first 3 months of pregnancy if the doctor can give your daughter a different medicine to treat malaria as this could have serious consequences for unborn children. 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, they 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.

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.

How to use Riamet® Dispersible

Malaria caused by *Plasmodium falciparum* is a serious, life-threatening disease and must be fully treated. Therefore, it is very important that Riamet Dispersible is 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.

Follow your doctor's instructions exactly.

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

Give 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 fill the cup with some water (approximately 10 ml) and ensure your child drinks it all.

After the 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 doctor.

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:

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

4th dose:	3 tablets	2 tablets	1 tablet
5th dose:	3 tablets	2 tablets	1 tablet
6th dose:	3 tablets	2 tablets	1 tablet
Total	18 tablets	12 tablets	6 tablets

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

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 your child has forgotten to take a dose, 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 many more tablets than prescribed by the doctor, you should immediately consult a doctor for your child or go to 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, 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

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 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 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 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 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 contains

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, maltodextrin.

Swissmedic number

58528

Availability/pack sizes

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

Pack contains 12 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 May 2020.