

Riamet®

Artemether and lumefantrine

Consumer Medicine Information

What is in this leaflet?

This leaflet answers some common questions about Riamet. It does not contain all the available information. It does not take the place of talking to your doctor or pharmacist.

The information in this leaflet was last updated on the date listed on the final page. Some more recent information on the medicine may be available.

Speak to your pharmacist or doctor to obtain the most up to date information on the medicine. You can also download the most up to date leaflet from www.novartis.com.au.

Those updates may contain important information about the medicine and its use of which you should be aware.

All medicines have risks and benefits. Your doctor has weighed the risks of you taking this medicine against the benefits they expect it will provide.

If you have any concerns about this medicine, ask your doctor or pharmacist.

Keep this leaflet with the medicine.

You may need to read it again.

What Riamet is used for

Riamet contains two antimalarial medicines, artemether and lumefantrine. These ingredients work together to kill the Plasmodium falciparum parasite in uncomplicated or mixed infections of malaria.

Malaria commonly occurs in sub-tropical and tropical areas.

Riamet is used to treat malaria acquired in areas where the parasite may be resistant to other anti-malarial medicines.

Malaria is an infectious mosquito-borne disease, spread to humans by the bite of the Anopheles mosquito. The mosquito carries parasites and injects them into the bloodstream when it bites a person.

The parasites infect red blood cells, causing fever, chills, a general feeling of unwell (malaise), cough, nausea, headaches, vomiting and diarrhoea. Not all symptoms need to be present to suggest that you have malaria.

Ask your doctor if you have any questions about why this medicine has been prescribed for you.

Your doctor may have prescribed it for another purpose.

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

It is not addictive.

Riamet is suitable for adults, adolescents, and children over 12 years of age who weigh 35 kg or more.

Before you take Riamet

When you must not take it

Do not take this medicine to prevent getting a malaria infection.

Do not take this medicine if you have a severe malaria infection.

Severe malaria is a malaria infection that affects the brain, lungs or kidneys.

Do not take Riamet if you are allergic to artemether or lumefantrine (the active ingredients) or to any of the other ingredients listed at the end of this leaflet.

If you think you may be allergic to Riamet, ask your doctor for advice.

Some of the symptoms of an allergic reaction may include:

- shortness of breath, wheezing or difficulty breathing
- swelling of the face, lips, tongue or other parts of the body
- rash, itching or hives on the skin.

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

Riamet may affect your developing baby especially if you take it during the first three (3) months of pregnancy. There are potential serious consequences for the foetus. It may be possible for the doctor to give an alternative medicine during this time.

Take Riamet in the later stages of pregnancy only if clearly necessary.

Your doctor will discuss with you the potential risks and benefits of taking Riamet during pregnancy.

Use effective contraception measures to prevent pregnancy, before you take Riamet. If you are taking hormonal birth control medicine, you should also use an additional method of birth control.

Women who are capable of becoming pregnant are advised to use

an effective method of contraception whilst on Riamet treatment, and until the start of the next menstruation after treatment.

Do not breast-feed while you are taking this medicine and for at least four (4) weeks after taking the last tablet.

It is not known if the active ingredient in Riamet passes into the breast milk and could affect your baby.

Do not take Riamet after the expiry date printed on the pack or if the packaging is torn or shows signs of tampering.

In that case, return it to your pharmacist.

Do not take Riamet until you tell your doctor about any other medical conditions that you have and any other medicines that you are taking before you start taking Riamet.

Your doctor may not want you to take Riamet or he/she may need to take special precautions if you have certain medical conditions or are taking certain medicines.

Before you start to take it

Tell your doctor if you have, or have ever had, any of the following:

- an abnormal electrical signal called "prolongation of the QT interval".
- a problem with your heart rhythm, heart rate, severe heart disease or any other heart problem
- a family history of heart rate or rhythm problems, or sudden death
- low blood electrolyte levels such as potassium or magnesium
- severe liver or kidney problems
- allergies to any other medicines, foods, dyes or preservatives.

Taking other medicines

Tell your doctor if you are taking, or have recently taken, any other

medicines, including medicines that you buy without a prescription from a pharmacy, supermarket or health food shop.

Some medicines and Riamet may interfere with each other. Some of these medicines include:

- other medicines used to treat malaria
- anti-retroviral medicines or protease inhibitors (used to treat HIV infections or AIDS)
- hormonal birth control medication (as you should follow an additional method of birth control whilst taking Riamet)
- medicines used to treat an abnormal heart rhythm, rhythm disturbance or affect heart beat (e.g. flecainide, metoprolol)
- medicines that can have side effects on your heart, including some medicines used to treat depression or mental illnesses (such as imipramine, amitriptyline, clomipramine),
- rifampicin, an antibiotic used to treat leprosy or tuberculosis
- some antibiotic medicines (e.g. macrolides, fluoroquinolones, and imidazole)
- cisapride, a medicine used to treat stomach disorders (such as hyperacidity, reflux and ulcers)
- triazole antifungal agents (e.g. fluconazole, itraconazole)
- certain medicines used to treat allergies or inflammation (e.g. non-sedating antihistaminics such as terfenadine or astemizole)
- a variety of other medicines that are removed from your body through your liver
- certain medicines used to treat epilepsy (such as carbamazepine, phenytoin)
- St John's wort (*Hypericum perforatum*), a medicinal plant extract that is used to relieve some temporary feelings of sadness or low mood

You may need to take different amounts of your medicines or you may need to take different medicines. Your doctor and pharmacist have more information.

If you have not told your doctor about any of these things, tell him/her before you start taking this medicine.

How to take Riamet

Follow all directions given to you by your doctor and pharmacist carefully.

They may differ from the information contained in this leaflet.

If you do not understand the instructions on the label, ask your doctor or pharmacist for help.

How much to take

Your doctor will tell you exactly how many Riamet tablets to take.

For adults and children over 12 years of age who weigh 35 kg or more, the recommended course of treatment consists of 6 doses taken over 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 recommended dose.

When to take it

Start treatment at the time of diagnosis by a doctor.

Unless your doctor tells you otherwise, take the six doses over 3 days as follows:

1. Take the first dose (4 tablets) as soon as possible after malaria is diagnosed.
2. Take the second dose (4 tablets) 8 hours after the first dose.
3. Take the third dose (4 tablets) 24 hours (exactly one day) after the first dose.
4. Take the fourth dose (4 tablets) 36 hours after the first dose.

5. Take the fifth dose (4 tablets) 48 hours (exactly 2 days) after the first dose.
6. Take the sixth dose (4 tablets) 60 hours after the first dose.

To benefit from the full therapeutic effect, the full course of medication must be taken over the 60 hours at the intervals as indicated.

How to take it

Swallow each dose (4 tablets) with a full glass of water or with drinks rich in fat (e.g. milk).

Do not break the tablets.

If possible, take the tablets with food or immediately after some food rich in fat.

If you are too unwell to eat, still take the tablets.

People with malaria often do not feel like eating, but you should try to eat normally as soon as you can tolerate food. Taking Riamet with food increases the amount of medicine that is absorbed into the body. This helps to kill the malaria parasite more effectively and reduces the risk of a relapse (a return of the malaria infection).

If you vomit within 1 hour of taking the tablets, take another dose as soon as you can. Then contact your doctor or pharmacist immediately. You may need to take another dose or get a prescription for more tablets.

If you are unsure about how much Riamet to take, or when to take it, please ask your doctor or pharmacist.

How long to take it

Continue taking Riamet tablets for the full course of treatment recommended by your doctor.

It is extremely important for you to take this medicine exactly as directed by your doctor and for the full course of treatment, even if you begin to feel better before you have finished the tablets. If you stop taking Riamet

tablets too soon, your symptoms may return.

Do not miss any doses.

Falciparum malaria is a serious, life-threatening disease that requires complete cure.

If you forget to take it

If you miss a dose, take the missed dose as soon as you remember, and then go back to the schedule prescribed by your doctor.

Do not take a double dose to make up for the one that you missed.

Your chance of an unwanted side effect may be increased if you do.

If you have trouble remembering when to take your medicine, ask your pharmacist for some hints.

If you take too much (overdose)

If you think that you or anyone else may have taken too much Riamet, immediately:

- **telephone your doctor or the Poisons Information Centre (telephone 13 11 26),**
- **or go to Accident and Emergency at your nearest hospital**

Keep the telephone numbers for these places handy.

Do this even if there are no signs of discomfort or poisoning.

You may require medical attention.

Remember to take your medicine with you, and show it to your doctor or to the staff of the emergency unit.

If you have run out of tablets, take the empty packaging along with you.

While you are taking Riamet

Things you must do

Contact your doctor immediately if your condition worsens, or if you feel too unwell to eat and drink.

Your doctor may want to perform a test called an electrocardiogram (ECG) and check the levels of electrolytes (such as potassium and magnesium) in your blood before and during treatment.

Tell your doctor if don't feel like eating while you are taking Riamet.

People with malaria usually don't feel like eating. However, eating may help to stop the malaria coming back.

Tell your doctor if you keep vomiting.

If you keep vomiting, the medicine may not work properly. Your doctor may need to give you another treatment.

Tell your doctor if your symptoms are not improving or if they become worse after starting Riamet.

This may mean that you need a different treatment for your malaria.

Tell your doctor immediately if you find out that you are pregnant while taking Riamet.

If you are about to be started on any new medicine, remind your doctor and pharmacist that you are taking Riamet.

Tell any doctor, dentist or pharmacist who treats you that you are taking Riamet.

Things you must not do

Do not give this medicine to anyone else, even if their condition seems similar to yours.

Do not use it to treat any other complaints unless your doctor tells you to.

Things to be careful of

If you feel ill again, especially if you develop a fever after finishing your treatment, see your doctor immediately.

A further course of treatment with Riamet may be necessary if the malaria infection returns (i.e. you have a relapse) or you are reinfected with *Plasmodium falciparum* after having been cured.

Avoid grapefruit juice whilst taking this medicine.

Be careful driving, operating machinery or doing jobs that require you to be alert while you are taking Riamet until you know how it affects you.

This medicine may make some people feel sleepy, dizzy or weak. If you have any of these symptoms, do not drive or do anything else that could be dangerous.

Side effects

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are taking Riamet.

All medicines can have side effects. Sometimes they are serious, most of the time they are not. You may need medical treatment if you get some of the side effects. You may not be able to tell the difference between side effects of Riamet and the symptoms of malaria itself.

Do not be alarmed by these lists of possible side effects.

You may not experience any of them. Most of the side effects are mild to moderate and will generally disappear after a few days to a few weeks from treatment.

Ask your doctor or pharmacist to answer any questions you may have.

Tell your doctor if you notice any of the following and they worry you:

- headache, loss of appetite

- stomach pain
- stomach problems
- nausea (feeling sick) or vomiting
- diarrhoea
- unusual tiredness or general weakness
- difficulty sleeping or sleepiness
- aching muscles or joints
- unsteadiness when walking
- tingling or numbness of the hands or feet
- sore throat
- cough
- fever
- shivering
- itching on the skin or a rash

Tell your doctor immediately if any of the following happen:

- decreased feeling of sensitivity (especially of the skin)
- abnormal walk or inability to co-ordinate body movements
- sudden signs of allergy such as rash, itching or hives on the skin; swelling of the face, lips, tongue or other parts of the body; wheezing or troubled breathing
- unusual bleeding or bruising under the skin
- feeling of fast or irregular heart beat (palpitations)
- dizziness, lightheadedness, fainting or near fainting
- involuntary muscle contractions, sometimes in rapid spasms
- unexplained persistent nausea
- signs of a possible liver problem such as persistent pain in the upper right abdomen, yellowing of the skin and/or eyes, dark urine or pale bowel motions.

Some side effects may not give you any symptoms and can only be found when tests are done. Some of these side effects include:

- heart rhythm disturbances (called QTc prolongation or abnormal ECG heart tracing)

Tell your doctor if you notice anything else that is making you feel unwell.

Some people may have other side effects not yet known or mentioned in this leaflet.

After taking Riamet

Storage

Keep your medicine in the original container until it is time to take a dose.

Store it in a cool dry place.

Do not store Riamet or any other medicine in the bathroom or near a sink.

Do not leave it in the car or on window sills.

Keep this medicine where children cannot reach it.

A locked cupboard at least one-and-a-half metres above the ground is a good place to store medicines.

Disposal

If your doctor tells you to stop taking this medicine or the expiry date has passed, ask your pharmacist what to do with any medicine you have left over.

Product description

What it looks like

Riamet tablets are yellow, round, flat tablets marked with N/C and a score line on one side and CG on the other side. Each carton contains 24 tablets.

Ingredients

Active Ingredients

Each RIAMET tablet contains:

- artemether 20 mg and
- lumefantrine 120 mg.

Inactive Ingredients

RIAMET tablets also contain:

- cellulose - microcrystalline (E460)
- croscarmellose sodium
- hypromellose (E 464)
- magnesium stearate (E 572)
- polysorbate 80
- silica-colloidal anhydrous

Excipients with known effect: sugars and latex (in trace amounts).

Riamet tablets do not contain lactose, sucrose, gluten, tartrazine or any other azo dyes.

Sponsor

Riamet tablets are supplied in Australia by:

NOVARTIS Pharmaceuticals
Australia Pty Limited

ABN 18 004 244 160

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Telephone: 1 800 671 203

Web site: www.novartis.com.au

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This leaflet was prepared in
June 2020.

Australian Registration Number:

Riamet tablet: AUST R 90011

This leaflet (ria240620c) was
prepared based on PI (ria240620i)