

RIAMET® TABLET

Artemether/Lumefantrine (20mg/120mg)

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What Riamet is used for

Riamet is used to treat adults, infants and children with malaria infections caused by *Plasmodium falciparum* (a type of malaria parasite) or with mixed infections that include *Plasmodium falciparum*.

Riamet is also recommended for malaria infections acquired in areas where malaria parasites may be resistant to other anti-malarial medicines.

Most tourists and business travellers, who are considered to be non-immune will be able to get prompt medical attention if malaria is suspected. However, a small number of people at risk of infection may be unable to obtain such care within 24 hours of the onset of symptoms, particularly if they are in an isolated location far from medical services. In such cases, they are given Riamet by their doctor for self-administration. ("stand-by emergency treatment").

How Riamet works

Riamet belongs to the group of medicines known as anti-malarials, i.e. medicines used to treat certain types of malaria infections. It destroys the malaria parasites (tiny organisms consisting of a single cell that are found inside the red blood cells).

Before you use Riamet

It is important to tell your doctor if you have other medical problems or if you are taking other medicines.

Follow all the doctor's instructions carefully. They may differ from the

general information contained in this leaflet.

When you must not use it

Do not take Riamet

- If you are allergic (hypersensitive) to artemether, lumefantrine, or any of the other ingredients of the Riamet tablets listed at the end of this leaflet. If you think you may be allergic, ask your doctor for advice.
- If you have a severe type of malaria infection that affects the brain, or any other severe complications of malaria (for example affecting the lungs or kidneys)
- If you have a heart condition, such as changes in the rhythm or rate of the heart beat, slow heart beat, or severe cardiac disease
- If any member of your family (e.g. parents, grandparents, brothers and sisters) has died suddenly due to a heart rate problem or is known to have been born with heart rate problems
- If you have low blood levels of electrolytes such as potassium or magnesium

If any of these apply to you, do not take Riamet and tell your doctor.

Pregnancy

If you are pregnant, think you may be pregnant or become pregnant while taking Riamet, tell your doctor. Riamet must not be used during the first 3 months of pregnancy if it is possible for the doctor to give an alternative medicine as there are potential serious consequences for the fetus. In later stages of pregnancy, you should take Riamet only if clearly necessary. Your doctor will discuss with you the potential risk of taking Riamet during pregnancy.

Breast-feeding

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

Before you start to use it

If any of these apply to you, tell your doctor before taking Riamet.

- If you have severe liver or kidney problems

- If you have a heart disorder, such as an abnormal electrical signal called "prolongation of the QT interval"

Infants and Children

Riamet tablets are suitable for use in children who weigh 5 kg or more. Specific dosage recommendations can be found in Riamet's Package Insert.

Riamet is not recommended for use in infants weighing less than 5 kg.

Older people (65 years and above)

No special precautions or dosage adjustments are considered to be necessary.

Females of childbearing potential

Females who are capable of becoming pregnant are advised to use an effective method of contraception during travel with standby emergency treatment, while on Riamet treatment, and until the start of the next menstruation after treatment. If you are taking hormonal birth control medicine, you should also use an additional method of birth control.

Taking other medicines

Tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription, because these might interact with Riamet.

Ask your doctor or pharmacist if you are not sure whether your medicine is one of the medicines listed below.

Some medicines must not be taken with Riamet. These include:

- certain medicines used for the treatment of heart rhythm disturbances (e.g. flecainide, metoprolol)
- certain medicines used to treat depression (such as imipramine, amitriptyline, clomipramine)
- certain types of medicine used to treat infections, such as:
 - rifampicin, an antibiotic to treat leprosy or tuberculosis
 - antibiotics, including medicines of the following

classes: macrolides,
fluoroquinolones, imidazole

- triazole antifungal agents
- certain medicines used to treat allergies or inflammation (e.g. non-sedating antihistaminics such as terfenadine or astemizole)
- a medicine called cisapride used to treat stomach disorders
- certain medicines used to treat epilepsy (such as carbamazepine, phenytoin)
- St John's wort (*Hypericum perforatum*) a medicinal plant or extract of this medicinal plant used to treat for example depressed mood

Tell your doctor if you are taking:

- any other medicines to treat malaria
- any anti-retroviral medicines or protease inhibitor (used to treat HIV infections or AIDS)
- an hormonal birth control medicine (in this case you should follow an additional method of birth control)

How to use Riamet

Always take this medicine exactly as your doctor or pharmacist has told you. Do not exceed the recommended dose prescribed by your doctor.

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

The tablets should be taken with food or drinks rich in fat (e.g. milk). Diets (with fat content between 30 to 60g/day) or breast milk are also fine. Grapefruit juice should be avoided. If you are too unwell to eat or drink, you should still take Riamet as prescribed and contact your doctor.

Start treatment at the time of diagnosis by a doctor or at first sign of symptoms if using standby treatment. Riamet for self-administered standby emergency treatment should be taken only when prompt medical help is not available (see also "What Riamet is used for"). However, go to the nearest emergency unit as soon as possible after starting treatment.

How much to use

A six-dose regimen over 3 days is recommended, as described below:

Adults and adolescents weighing 35 kg and above

1st dose, at the time of initial diagnosis
4 tablets

2nd dose, at 8 hours after 1st dose
4 tablets

3rd dose, at 24 hours after 1st dose
4 tablets

4th dose, at 36 hours after 1st dose
4 tablets

5th dose, at 48 hours after 1st dose
4 tablets

6th dose, at 60 hours after 1st dose
4 tablets

Total number of tablets: 24 tablets

To benefit from the full therapeutic effect, the full course of medication (i.e. all 6, 12, 18 or 24 tablets) must be taken over the 60 hours at intervals as indicated.

- For administration to small children and infants, the tablet(s) may be crushed. If there is no specific pack size for the treatment of children, a 24-tablet pack size will be provided. Follow carefully the dosage prescribed by the doctor and use only the number of tablets needed. Return the remaining tablets to your pharmacist.
- If you vomit within one hour of taking the tablets, contact your doctor or pharmacist immediately. You may need to take another dose.

How long to use Riamet

The tablets have to be taken at the intervals described under "How much to use".

Continue taking Riamet for as long as your doctor recommends.

If you forget to use Riamet

Try to make sure that you do not miss any doses. However, if you do forget a dose of Riamet, take the missed dose as soon as you realise that you have forgotten it. Do not take a double dose to make up for individual doses that you have forgotten. Then take the next dose at the usual time.

If you use too much (overdose)

If you have accidentally taken too many tablets, talk to your doctor straight

away, or go to your nearest emergency unit. 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 using Riamet

Things you must do

If you are infected with both *Plasmodium falciparum* and *Plasmodium vivax*, your doctor will prescribe another medicine for you to take after completing Riamet treatment. If your condition worsens, or if you feel too unwell to eat and drink, contact your doctor immediately. 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.

If you are taking or have taken any other medication for the treatment of malaria, talk to your doctor, because some of these medicines must not be given together with Riamet.

Things you must not do

Do not stop taking the medicine unless advised by your doctor.

Things to be careful of

A second course of Riamet may be necessary if the malaria infection returns (relapse) or if you are re-infected with *Plasmodium falciparum* after having been cured.

Side effects

As with all medicines, patients treated with Riamet may experience side effects, although not everyone gets them.

Most of the side effects are mild to moderate and will generally disappear after a few days to a few weeks from treatment. Some side effects are more commonly reported in children and others are more commonly reported in adults. In cases where there is a difference, the frequency listed below is the more common one.

Some side effects could be serious

This side effect is rare (affecting between 1 and 10 in every 10,000 patients)

- Allergic reaction (may include rash, itching, swelling mainly of

the face or throat, difficulty breathing or swallowing, or dizziness)

This side effect is uncommon, it may affect between 1 and 10 in every 1,000 patients:

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

Some side effects are very common
These side effects may affect more than 10 in every 100 patients

- Loss of appetite
- Trouble with sleeping
- Headache
- Dizziness
- Fast heart beat
- Cough
- Stomach pain
- Nausea (feeling sick) and / or vomiting
- Aching joints and muscles
- Tiredness and general weakness.

Some side effects are common
These side effects may affect between 1 and 10 in every 100 patients

- Involuntary muscle contractions (sometimes in rapid spasms)
- Diarrhea
- Itching on the skin or a rash
- Symptoms such as unexplained persistent nausea, stomach problems, loss of appetite or unusual tiredness or weakness (signs of liver problems).

If any of these affects you severely, tell your doctor.

If you notice any other side effects not mentioned in this leaflet, please inform your doctor or pharmacist as soon as possible.

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by visiting the website nptra.gov.my [Public→ Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI)]

Storage and disposal of Riamet

Storage:

- Do not use the tablets after the expiry date shown on the box.
- Store in the original package in order to protect from moisture.
- Do not store above 30°C.

- Keep out of the sight and reach of children.

Disposal:

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

Product Description

What it looks like

Riamet is supplied as tablets which are yellow, round, flat and scored on one side. “N/C” is imprinted on one side and “CG” on the other. Each tablet contains 20mg of artemeter and 120mg of lumefantrine.

Ingredients

- *Active ingredients*

The active substances of Riamet are artemether and lumefantrine.

- *Inactive ingredients*

The other ingredients are polysorbate 80, hypromellose, microcrystalline cellulose, silica colloidal anhydrous, croscarmellose sodium and magnesium stearate.

MAL Number

MAL20032242ARZ

Manufacturer

Novartis Saglik Gida Ve Tarim, Urunleri, Kurtkoy, Istanbul, Turkey.

Product Registration Holder

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Date of revision

21/02/2022

Serial number

NPRA (R1/1) 19052022/141