

Drug Regulatory Affairs

COARTEM[®] / RIAMET[®] Dispersible
(artemether/lumefantrine)

20 mg/120 mg Dispersible Tablets

Basic Patient Leaflet

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Read all of this leaflet carefully before you start using COARTEM[®] / RIAMET[®] Dispersible

Keep this leaflet. You may need to read it again.

This medicine has been prescribed only for you. Do not give it to anybody else or use it for any other illnesses.

If you have further questions, please ask your doctor or pharmacist.

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1 What Coartem/Riamet Dispersible is and what it is used for

Each Coartem/Riamet Dispersible tablet contains 20 mg of artemether and 120 mg of lumefantrine.

Coartem/Riamet Dispersible 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).

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

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

Most tourists and travellers, who are considered to be non-immune (i.e. they have no immune protection against malaria), will be able to get prompt medical attention if malaria is suspected. However, a small number of children 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, the parent or caregiver is given Coartem/Riamet Dispersible by their doctor to administer to the travelling child (= “standby emergency treatment”).

You should be aware that self-administered medication of this kind is a first-aid measure to be taken only if you suspect your child has a *falciparum* malaria infection. If this happens, you should still seek medical advice as soon as possible.

Coartem/Riamet Dispersible is not suitable for preventing malaria, nor for treating severe malaria (e.g. affecting the child’s brain, kidneys, or lungs).

2 Before you give your child Coartem/Riamet Dispersible

It is important to tell your doctor if your child has other medical problems or if he/she is taking other medicines.

Do not give Coartem/Riamet Dispersible:

- **If your child is allergic** (hypersensitive) to artemether, lumefantrine, or any of the other ingredients of the Coartem/Riamet Dispersible tablets listed at the end of this leaflet.

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

- **If your child has** 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 your child is** in the first 3 months of pregnancy or intends to become pregnant and it is possible for the doctor to give an alternative medicine.
- **If your child has** 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 child's family (i.e. 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 your child is** being treated with medicines that affect the heart beat (known as anti-arrhythmics) (see "Taking other medicines").
- **If your child has** low blood levels of electrolytes such as potassium or magnesium.

If any of these apply to your child, **tell your doctor without giving your child Coartem/Riamet Dispersible.**

Take special care with Coartem/Riamet Dispersible:

- If your child has severe liver or kidney problems.
- If your child has a heart disorder, such as an abnormal electrical signal called "prolongation of the QT interval".

If any of these conditions apply to your child, **tell your doctor before you give your child Coartem/Riamet Dispersible.**

If your child is infected with both *Plasmodium falciparum* and *Plasmodium vivax*. Your doctor will prescribe another medicine for your child to take after completing Coartem/Riamet Dispersible treatment.

If your child's condition worsens, or he/she feels 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 child's blood before and during treatment.

If your child is taking or has taken any other medication for the treatment of malaria, talk to your doctor, because some of these medicines must not be given together with Coartem/Riamet Dispersible.

Taking other medicines

Tell your doctor or pharmacist if your child is taking or has recently taken any other medicines, including any you may have bought without a prescription.

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

- certain medicines used for the treatment of heart rhythm disturbances (e.g. flecainide, metoprolol),
- certain medicines used to treat depression (e.g. imipramine, amitriptyline, clomipramine),
- certain types of medicine used to treat infections such as:
 - 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.

Tell your doctor if you are giving your child:

- any other medicines to treat malaria.
- any anti-retroviral medicines or protease inhibitor (used to treat HIV infections or AIDS).

Giving Coartem/Riamet Dispersible with food and drink

The Coartem/Riamet Dispersible dose should be immediately followed by food or drinks rich in fat (e.g. milk).

Infants and Children

Coartem/Riamet Dispersible is suitable for use in children who weigh 5 kg or more. Specific dosage recommendations can be found in section 3 “How to give Coartem/Riamet Dispersible”.

Pregnancy

If your daughter is pregnant, if you think she may be pregnant or if she becomes pregnant while taking Coartem/Riamet Dispersible, tell your doctor. Coartem/Riamet Dispersible 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 foetus. In later stages of pregnancy, you should give Coartem/Riamet Dispersible to your daughter only if clearly necessary. Your doctor will discuss with you and your daughter the potential risk of taking Coartem/Riamet Dispersible during pregnancy.

Women of childbearing potential

Adolescent women who are capable of becoming pregnant are advised to use an effective method of contraception during travel with standby emergency treatment, while on Coartem/Riamet Dispersible treatment, and until the start of the next menstruation after treatment.

Breast-feeding

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

Driving and using machines

Coartem/Riamet Dispersible may make your child feel sleepy, dizzy or generally weak. If this happens, do not let him/her drive or use machines.

3 How to give Coartem/Riamet Dispersible to your child

How to give Coartem/Riamet Dispersible

Follow your doctor's instructions carefully. Do not exceed the recommended dose.

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

Place the Coartem/Riamet Dispersible tablets in a small amount of water (approximately 10 mL per tablet) in a cup. Allow the tablet(s) to disintegrate and stir gently before giving the solution to your child to drink. Afterwards, immediately rinse the cup with an additional small amount of water (approximately 10 mL) and give it to your child to drink completely.

The tablets should be followed by food or drinks rich in fat (e.g. milk). If your child is too unwell to eat or drink, you should still give Coartem/Riamet Dispersible 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. Self-administration of Coartem/Riamet Dispersible to your child for standby emergency treatment should be given only when prompt medical help is not available (see also "What Coartem/Riamet Dispersible is and what it is used for"). However, go to the nearest emergency unit as soon as possible after starting treatment.

How much to Coartem/Riamet Dispersible give

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

Infants and children weighing 5 kg to less than 35 kg and 12 years of age or less

Dose/time	Body weight 5 kg to less than 15 kg	Body weight 15 kg to less than 25 kg	Body weight 25 kg to less than 35 kg
1 st dose, at the time of initial diagnosis	1 tablet	2 tablets	3 tablets
2 nd dose, at 8 hours after 1 st dose	1 tablet	2 tablets	3 tablets
3 rd dose, at 24 hours after 1 st dose	1 tablet	2 tablets	3 tablets
4 th dose, at 36 hours after 1 st dose	1 tablet	2 tablets	3 tablets
5 th dose, at 48 hours after 1 st dose	1 tablet	2 tablets	3 tablets
6 th dose, at 60 hours after 1 st dose	1 tablet	2 tablets	3 tablets
Total number of tablets:	6 tablets	12 tablets	18 tablets

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

- If your child vomits within one hour of taking the tablets, contact your doctor or pharmacist immediately. You may need to give your child another dose.

If you give your child more Coartem/Riamet Dispersible than you should

If you have accidentally given too many tablets, **talk to your doctor straight away**, or go to your nearest emergency unit. Your child may require medical attention. Remember to take the 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.

If you forget to give Coartem/Riamet Dispersible

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

What else should you be aware of while giving Coartem/Riamet Dispersible?

A second course of Coartem/Riamet Dispersible may be necessary if the malaria infection returns (relapse) or if your child is re-infected with *Plasmodium falciparum* after having been cured.

4 Possible side effects

Like all medicines, Coartem/Riamet Dispersible can lead to 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 of treatment.

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)

Some side effects are very common

These side effects may affect more than 10 in every 100 patients

- Loss of appetite
- Cough
- Vomiting

If any of these affects your child severely, **tell your doctor**.

Some side effects are common

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

- Headache
- Dizziness
- Stomach pain
- Diarrhoea
- Nausea (feeling sick)
- Rash
- Aching joints and muscles
- Tiredness and general weakness
- 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 your child severely, **tell your doctor**.

Some side effects are uncommon

These side effects may affect between 1 and 10 in every 1,000 patients

- Trouble with sleeping
- Sleepiness
- Fast heart beat
- Itching on the skin

If any of these affects your child 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.

5 Storing Coartem/Riamet Dispersible

- Do not use the tablets after the expiry date shown on the box.
- Store in the original package.
- Do not store above 30°C.
- Protect from moisture.
- Keep out of the reach and sight of children.

6 Further information

What Coartem/Riamet Dispersible is

- The **active substances** of Coartem/Riamet Dispersible are artemether and lumefantrine.
- The **other ingredients** are microcrystalline cellulose, crospovidone, cherry dry flavour, croscarmellose sodium, saccharin sodium (8 mg per dispersible tablet), magnesium stearate, hypromellose, silica colloidal anhydrous, and polysorbate 80.

What Coartem/Riamet Dispersible looks like and contents of the pack

Coartem/Riamet Dispersible is supplied as dispersible tablets which are round, flat, and yellow. “CG” is imprinted on one side and “NVR” on the other. Each dispersible tablet contains 20 mg of artemether and 120 mg of lumefantrine.

Novartis Packs for the Private Market

Each pack contains 18 dispersible tablets. No specific pack for the treatment of children and infants is available. The 18-tablet pack should be used for these patients and the parent or caregiver should be given the necessary information for dosing based on body weight. Depending on the dose needed, it may not be necessary to use all the tablets in the pack, and any that are left over should be given to a pharmacist for disposal.

Novartis Packs for the Public Market

Coartem/Riamet Dispersible is available as wallet dosing cards specific for each body weight range.

For body weights of 5 kg to less than 15 kg: each wallet dosing card contains 6 dispersible tablets.

For body weights of 15 kg to less than 25 kg: each wallet dosing card contains 12 dispersible tablets.

For body weights of 25 kg to less than 35 kg: each wallet dosing card contains 18 dispersible tablets.

Marketing Authorisation Holder

Country specific.

Manufacturer

Country specific.

If you have any questions about this medicine, please contact your doctor or pharmacist.

This leaflet was last approved on: [country specific]