

Package leaflet: Information for the user
Artemether and Lumefantrine
80 mg/480 mg Tablet
artemether and lumefantrine

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. (See section 4).

What is in this leaflet

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1. What Artemether and Lumefantrine Tablet 80 mg/480 mg is and what it is used for

Artemether and Lumefantrine Tablet 80 mg/480 mg contains two substances called artemether and lumefantrine. They belong to a group of medicines called anti-malarials.

Artemether and Lumefantrine Tablet 80 mg/480 mg is only used for the treatment of acute uncomplicated malaria infections caused by a parasite called “Plasmodium falciparum”. This parasite is a tiny organism made up of one cell that is found inside red blood cells.

Artemether and Lumefantrine Tablet 80 mg/480 mg is used to treat adults, children and infants of 5 kg body weight and above.

Artemether and Lumefantrine Tablet 80 mg/480 mg is not used to prevent malaria or to treat severe malaria (where it has affected the brain, lungs or kidneys).

2. What you need to know before you take Artemether and Lumefantrine Tablet 80 mg/480 mg Do not take Artemether and Lumefantrine Tablet 80 mg/480 mg

- if you are allergic (hypersensitive) to artemether, lumefantrine, or any of the other ingredients of this medicine (listed in section 6).
- if you have a severe type of malaria infection where it has affected parts of your body such as the brain, lungs or kidneys.
- if you have a heart condition, such as changes in the rhythm or rate of the heart beat, a slow heart beat, or severe heart disease.
- if any member of your family (parents, grandparents, brothers or sisters) has died suddenly due to a heart problem or was born with heart problems.
- if your doctor has told you that you have low levels of electrolytes such as potassium or magnesium in your blood.

- if you are taking the following medicines: flecainide, metoprolol, imipramine, amitriptyline, clomipramine, certain antibiotics (macrolides, fluoroquinolones, imidazole), triazole antifungal agents, terfenadine, astemizole, cisapride (see also “Other medicines and Artemether and Lumefantrine Tablet 80 mg/480 mg”).
- if you are taking certain medicines (see also “Other medicines and Artemether and Lumefantrine Tablet 80 mg/480 mg”). If any of the above apply to you, tell your doctor without taking Artemether and Lumefantrine Tablet 80 mg/480 mg.

Warnings and precautions

Talk to your doctor or pharmacist before taking Artemether and Lumefantrine Tablet 80 mg/480 mg:

- 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”.
- if you are infected with both the “Plasmodium falciparum” and “Plasmodium vivax” parasites.
- if you are taking or have taken any other medicines for the treatment of malaria. Some of these medicines must not be given together with Artemether and Lumefantrine Tablet 80 mg/480 mg.
- if you are in the first 3 months of pregnancy or intend to become pregnant. Your doctor will try to give you an alternative medicine first.
- if you feel worse, or if you feel too unwell to eat and drink.

If any of these apply to you, talk to your doctor before you take Artemether and Lumefantrine Tablet 80 mg/480 mg.

Other medicines and Artemether and Lumefantrine Tablet 80 mg/480 mg

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines, including medicines obtained without a prescription.

In particular, do not take this medicine and tell your doctor if you are taking any of the following:

- medicines used to treat heart rhythm problems such as flecainide or metoprolol.
- medicines used to treat depression such as imipramine, amitriptyline or clomipramine.
- medicines used to treat infections called:
 - rifampin, an antibiotic to treat leprosy or tuberculosis
 - antibiotics, including the following types: macrolides, fluoroquinolones or imidazole,
 - triazole antifungal agents.
- medicines used to treat allergies or inflammation called “non-sedating antihistamics” such as terfenadine or astemizole.
- cisapride - a medicine used to treat stomach problems.
- 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.

If you are taking any of the above medicines, do not take Artemether and Lumefantrine Tablet 80 mg/480 mg. Please tell your doctor if you are taking:

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

Artemether and Lumefantrine Tablet 80 mg/480 mg with food and drink

Artemether and Lumefantrine Tablet 80 mg/480 mg should be taken with food or drinks rich in fat such as milk . Grapefruit juice should be used cautiously. Please ask your doctor for advice on the best food or drinks to take Artemether and Lumefantrine Tablet 80 mg/480 mg with.

Pregnancy and breast-feeding

Artemether and Lumefantrine Tablet 80 mg/480 mg is not recommended during the first 3 months of pregnancy if it is possible for the doctor to give an alternative medicine first. In the later stages of pregnancy, you should take Artemether and Lumefantrine Tablet 80 mg/480 mg if your doctor considers it appropriate for you.

Your doctor will discuss with you the potential risk of taking Artemether and Lumefantrine Tablet 80 mg/480 mg during pregnancy. If you are taking hormonal birth control medicine, you should also use an additional method of birth control for about one month.

You should not breast-feed while you are taking Artemether and Lumefantrine Tablet 80 mg/480 mg. Once you have stopped taking Artemether and Lumefantrine Tablet 80 mg/480 mg, you should wait at least 1 week before starting to breast-feed again.

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

Driving and using machines

Artemether and Lumefantrine Tablet 80 mg/480 mg may make you feel sleepy, dizzy or generally weak. If this happens to you, do not drive or use any tools or machines.

3. How to take Artemether and Lumefantrine Tablet 80 mg/480 mg

Always take this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

Taking Artemether and Lumefantrine Tablet 80 mg/480 mg

- the tablets should be taken with food or drinks rich in fat such as milk. Please ask your doctor for advice on the best food or drinks to take Artemether and Lumefantrine Tablet 80 mg/480 mg with.
- if you feel worse or are too unwell to eat or drink, please talk to your doctor.
- if you are sick (vomit) within 1 hour of taking the tablets take another dose. If in doubt, talk to your doctor.

Use in children

- when given to small children or infants, the tablets may be crushed.

When treating your child, a 24-tablet pack will be provided. Follow your doctor's instructions carefully and use only the number of tablets needed. Return the remaining tablets to your pharmacist.

How much to take or give

- six doses are taken over 3 days.
- the first dose should be taken as soon as possible and should be followed by five further doses at 8, 24, 36, 48 and 60 hours after the first dose, as described in the next section.
- when you take your first dose, work out the times you will need to take the rest of the doses at and write them down.
- all doses must be taken, and at the right times, to gain the full benefits of this medicine.

Adults and children weighing 35 kg and above

Take four tablets at each time interval. So you take or give:

- **1 tablet** as soon as possible, then
- **1 tablet** 8 hours later, then
- **1 tablet** 24 hours after the first dose, then
- **1 tablet** 36 hours after the first dose, then
- **1 tablet** 48 hours after the first dose and then

- the final **1 tablets** 60 hours after the first dose. This will mean you take or give a total of **6 tablets**.

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

If the malaria infection returns

A second course of Artemether and Lumefantrine Tablet 80 mg/480 mg may be necessary if the malaria infection returns, or if you are re-infected with the parasite “Plasmodium falciparum” after having been cured. If this happens to you please talk to your doctor.

If you take more Artemether and Lumefantrine Tablet 80 mg/480 mg than you should

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

If you forget to take Artemether and Lumefantrine Tablet 80 mg/480 mg

Try to make sure that you do not miss any doses. However, if you do forget a dose of Artemether and Lumefantrine Tablet 80 mg/480 mg, take the missed dose as soon as you remember unless it is almost time for your next dose. Then take your next dose at the usual time. Ask your doctor for advice. Do not take a double dose to make up for a forgotten dose.

If you stop taking Artemether and Lumefantrine Tablet 80 mg/480 mg

Do not stop taking your medicine unless your doctor tells you to. Always follow your doctor’s instructions carefully, and complete the course of medication.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

Most of the side effects are mild to moderate and generally disappear after a few days to a few weeks after 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 and need immediate medical attention. Rare (*may affect up to 1 in 1,000 people*)

If you get a rash, swelling of the face, lips, tongue or throat with difficulty in swallowing or breathing, tell your doctor straight away. These are signs of an allergic reaction.

Other side effects are:

Very common (*may affect more than 1 in 10 people*)

Fast heart beat, headache, dizziness, cough, being sick (vomiting), stomach pain, feeling sick (nausea), joints or muscles aching, loss of appetite, general weakness, tiredness, trouble with sleeping.

Common (*may affect up to 1 in 10 people*)

Involuntary muscle contractions (sometimes in rapid spasms), heart rhythm disturbances (called QTc prolongation), Symptoms such as unexplained persistent nausea, stomach problems, loss of appetite or unusual tiredness or weakness (signs of liver problems), diarrhoea, abnormal walking*),

tingling or numbness of the hands and feet^{*)}, a rash or itching on the skin, insomnia.

Uncommon (*may affect up to 1 in 100 patients*)

inability to coordinate movements^{*)}, decreased skin sensitivity^{*)}, sleepiness, itching rash.

^{*)} These side effects have been reported in adults and adolescents above 12 years of age.

Not known (*frequency cannot be estimated from the available data*)

Anaemia due to breakdown of red blood cells, which has been reported up to a few weeks after treatment has been stopped (delayed haemolytic anaemia).

Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet.

5. How to store Artemether and Lumefantrine Tablet 80 mg/480 mg

Keep this medicine out of the sight and reach of children.

Do not use Artemether and Lumefantrine Tablet 80 mg/480 mg after the expiry date which is stated on the carton. The expiry date refers to the last day of that month.

Do not store above 30°C.

Do not use Artemether and Lumefantrine Tablet 80 mg/480 mg if you notice that the pack is damaged or shows signs of tampering.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information What Artemether and Lumefantrine Tablet 80 mg/480 mg contains

- The active substances of Artemether and Lumefantrine Tablet 80 mg/480 mg are artemether and lumefantrine.
- The other ingredients are Microcrystalline Cellulose, Maize starch, Sorbitol, HPMC E 5, IPA, PVPK 30, Sodium Lauryl sulphate, Purified water, Purified Talc, Croscarmellose sodium, Magnesium Stearate, Silicon dioxide, Cross povidone, Dr coat- white and Tartrazine supra.

What Artemether and Lumefantrine Tablet 80 mg/480 mg looks like and contents of the pack

Artemether and Lumefantrine Tablet 80 mg/480 mg tablets are Yellowish Colour, caplet shaped, film coated tablet having breakline on one side and plain on other side.

Marketing Authorisation Holder

Aura Lifecare Pvt. Ltd.

S. No. 254/14/1, Jarod-Savli Road,

P.O.: Karachiya, Tal. Savli, Dist. Vadodara- 391 520,

Gujarat, India.

Manufacturer

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