

**Read this entire leaflet carefully before you start taking this medicine.**

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor or your pharmacist.
- This medicine has been prescribed for you personally and you should not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

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1. What is Artemether + Lumefantrine Tablets and what it is used for
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**1. WHAT IS ARTEMETHER + LUMEFANTRINE TABLETS AND WHAT IT IS USED FOR**

Artemether and Lumefantrine belong to a group of medicines called anti-malarials.

Artemether + Lumefantrine Tablet 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 + Lumefantrine Tablet is used to treat adults, children and infants of 5 kg body weight and above.

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

**2. BEFORE YOU TAKE ARTEMETHER + LUMEFANTRINE TABLETS**

**Do not take Artemether + Lumefantrine Tablets:**

if you are allergic to any of the ingredients.

- 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.

If any of the above apply to you, tell your doctor without taking Artemether + Lumefantrine Tablets.

**Take special care with Artemether + Lumefantrine Tablets**

Check with your doctor or pharmacist before taking Artemether + Lumefantrine Tablets:

- 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 + Lumefantrine Tablets.
- 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 + Lumefantrine Tablets.

**Taking other medications:**

Please tell your doctor or pharmacist if you are taking or have recently taken 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 + Lumefantrine Tablets.

Please tell your doctor if you are taking:

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

**Taking Artemether + Lumefantrine Tablets with food and drink:**

Artemether + Lumefantrine 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 + Lumefantrine Tablets with.

**Pregnancy:**

Tell your doctor if you are pregnant, think you may be pregnant or become pregnant while taking Artemether + Lumefantrine Tablets.

Artemether + Lumefantrine Tablets must not be used 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 + Lumefantrine Tablets. Only if clearly necessary.

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

**Breast-feeding:**

You should not breast-feed while you are taking Artemether + Lumefantrine Tablets. Once you have stopped taking Artemether + Lumefantrine Tablets, you should wait at least 1 week before starting to breast-feed again.

Ask your doctor or pharmacist for advice before taking any medicine during pregnancy or while you are breast-feeding.

**Driving and using machines:**

Artemether + Lumefantrine Tablets 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 + LUMEFANTRINE TABLETS**

Always take Artemether + Lumefantrine Tablets exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure.

**Taking Artemether + Lumefantrine Tablets**

- 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 + Lumefantrine Tablets 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.

**How much to take**

- 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.
- 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 (Body Weight > 35 Kg)**

1 tablet as a single dose at the time of diagnosis, 1 tablet after 8 hrs. and then 1 tablet 12 hourly for next two days (totally 6 tablets/ course).

**If the malaria infection returns**

A second course of Artemether/Lumefantrine Tablets 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 + Lumefantrine Tablets 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 + Lumefantrine Tablets:**

It is important to use each dose as scheduled. If you miss a dose, use it as soon as you remember. If it is near the time of the next dose, skip the missed dose and resume your usual dosing schedule. If you miss more than one dose, contact your health care professional to establish a new dosing schedule. Do not double the dose to catch up.

**If you stop taking Artemether + Lumefantrine Tablets**

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 product, ask your doctor or pharmacist.

**4. POSSIBLE SIDE EFFECTS**

Like all medicines, Artemether + Lumefantrine Tablet 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** (affecting less than 1 in 1,000 patients)

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** (affecting more than 1 in 10 patients)

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** (affecting less than 1 in 10 patients)

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** (*affecting less than 1 in 100 patients*)

inability to coordinate movements), decreased skin sensitivity), sleepiness, itching rash.

If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

## 5. HOW TO STORE ARTEMETHER + LUMEFANTRINE TABLETS

Do not store above 30°C, Protect from light

Keep out of the reach and sight of children.

**Keep Artemether + Lumefantrine Tablets and all medicines out of the reach of children.**

Do not use Artemether + Lumefantrine Tablets after the expiry date which is stated on the carton. The expiry date refers to the last day of that month.

Do not use Artemether + Lumefantrine Tablets if you notice that the pack is damaged or shows signs of tampering.

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.

## 6. FURTHER INFORMATION

**General information about the safe and effective use of Artemether + Lumefantrine Tablets.**

Medicines are sometimes prescribed for purposes other than those listed in patient information leaflets. Do not use Artemether/Lumefantrine Tablets for a condition for which it was not prescribed. Do not give Artemether/Lumefantrine Tablets to other people, even if they have the same symptoms that you have. It may harm them.

This patient information leaflet summarizes the most important information about Artemether/Lumefantrine Tablets. If you would like more information about Artemether/Lumefantrine Tablets talk with your healthcare provider. You can ask your healthcare provider or pharmacist for information about Artemether/Lumefantrine Tablets that is written for health professionals.

**What Artemether/Lumefantrine Tablets contains:**

Artemether/Lumefantrine Tablets contains the active ingredient Corn Starch, Colloidal silicon dioxide, Sodium Starch Glycolate, Hypromellose, Microcrystalline Cellulose, Hydroxy propyl cellulose, Magnesium Stearate

**What Artemether/Lumefantrine Tablets looks like and contents of the pack**

**Artemether/Lumefantrine Tablets will be packed in,**

Plain 25 micron Aluminium Foil/ 6-8 gsm HSL, (Width – 180 mm) with Clear PVC/PE/PVDC film  
250/25/60 gsm (Width -184 mm) Blister

Pack of 15 tablets, such 10 blisters in a box.

Supplier	Manufacturer
<p>Macleods Pharmaceuticals Ltd. 304, Atlanta Arcade, Marol Church Road, Andheri (East) Mumbai- 400 059, India Phone: +91-22-66762800 Fax: +91-22-2821 6599 Contact: Sandhya Jadhav Tel: 0091 22  28314611/28258944/28302293/ 28208971 Fax: 0091 28216599 Email: sjadhav@macleodspharma.com</p>	<p><b>Oxalis Labs</b> Village Theda, P.O Lodhimajra, Baddi, Distt. Solan, Himachal Pradesh, 174101, India Telephone: + 91-1795 650138 Fax: + 91-1795 661452</p>

**For any information about this medicinal product, please contact the local representatives of the supplier.**

Supplier	Manufacturer
<p>Macleods Pharmaceuticals Ltd. 304, Atlanta Arcade, Marol Church Road, Andheri (East) Mumbai- 400 059, India Phone: +91-22-66762800 Fax: +91-22-2821 6599 Email: sjadhav@macleodspharma.com vijay@macleodspharma.com</p>	<p><b>Oxalis Labs</b> Village Theda, P.O Lodhimajra, Baddi, Distt. Solan, Himachal Pradesh, 174101, India Telephone: + 91-1795 650138 Fax: + 91-1795 661452</p>