



BANGALORE, INDIA.

ARTEMETHER & LUMEFANTRINE TABLETS 20/120mg

COMBIART

1.6 PRODUCT INFORMATION

1.6.3 Patient information leaflet (PIL)

Enclosed

PATIENT INFORMATION LEAFLET

PATIENT INFORMATION LEAFLET: INFORMATION FOR THE USER

Artemether/Lumefantrine 20mg/120mg Tablets *

Artemether, 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, healthcare provider 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, healthcare provider or pharmacist. This includes any possible side effects not listed in this leaflet.

What is in this leaflet:

1. What Artemether/Lumefantrine 20mg/120mg Tablets is and what it is used for
2. What you need to know before you take Artemether/Lumefantrine 20mg/120mg Tablets
3. How to take Artemether/Lumefantrine 20mg/120mg Tablets
4. Possible side effects
5. How to store Artemether/Lumefantrine 20mg/120mg Tablets
6. Contents of the pack and other information

1. WHAT ARTEMETHER/LUMEFANTRINE 20MG/120MG TABLETS IS AND WHAT IT IS USED FOR

This medicine is an antimalarial. It is used to treat a certain type of malaria infection in adults and children who weigh at least 5 kg.

Artemether/Lumefantrine 20mg/120mg Tablets contains two antimalarial drugs, artemether and lumefantrine in fixed dose, which work together to kill the malaria parasite (a tiny organism that is found inside the red blood cells).

Your doctor has found that you have malaria and so has prescribed Artemether/Lumefantrine 20mg/120mg Tablets. It is indicated only for the treatment of so called uncomplicated malarial attacks due to *Plasmodium falciparum* (a particular type of malaria parasite) against which the medicine is active.

For complete cure, it is important that you complete the prescribed dose as advised by your doctor, pharmacist or health care provider.

2. WHAT YOU NEED TO KNOW BEFORE YOU TAKE ARTEMETHER/LUMEFANTRINE 20MG/120MG TABLETS

Do not take Artemether/Lumefantrine 20mg/120mg Tablets:

- if you are hypersensitive (allergic) to artemether, lumefantrine, or any of the other ingredients of Artemether/Lumefantrine 20mg/120mg Tablets (see section 6, **What Artemether/Lumefantrine 20mg/120mg Tablets contains**).

Warnings and precautions

If you are pregnant, you must tell your doctor or health care provider. Artemether/Lumefantrine 20mg/120mg Tablets should only be used in pregnancy if it is considered absolutely necessary (see below).

Pregnancy and breast-feeding

Artemether/Lumefantrine 20mg/120mg Tablets can change your electrical recording of the heart (electrocardiogram, ECG). Therefore, before taking Artemether/Lumefantrine 20mg/120mg Tablets, inform your doctor or health care provider if you have:

- any condition with certain abnormal ECG changes
- a salt imbalance in the blood, especially low concentrations of potassium in the blood (hypokalaemia) which are currently not corrected by treatment
- a very slow heart rate (bradycardia)
- a weak heart (heart failure)
- history of abnormal heart rhythms (arrhythmias)

Also, inform your doctor or health care provider:

- If you are taking any medicine that lowers your blood potassium levels.
- If you are taking other medicines that result in certain abnormal ECG changes (see below, **Other medicines and Artemether/Lumefantrine 20mg/120mg Tablets**).

If you experience palpitations or an irregular heartbeat during treatment, you should tell your doctor immediately. He/she may wish to perform an ECG.

The use of Artemether/Lumefantrine 20mg/120mg Tablets has not been investigated in patients with kidney or liver disease. If you have any such condition, you should inform your doctor or health care provider before taking Artemether/Lumefantrine 20mg/120mg Tablets.

Artemether/Lumefantrine 20mg/120mg Tablets should not be used in patients with severe malaria for malaria prophylaxis or in combination with other drugs against malaria, unless your doctor or health care provider considers this appropriate in your particular case.

You should inform your doctor or health care provider about all malaria medicines that you have taken the last months, as the appropriateness of using Artemether/Lumefantrine 20mg/120mg Tablets may depend on this.

Artemether/Lumefantrine 20mg/120mg Tablets may lower the effects of hormonal contraceptives. Therefore a different or an additional method of contraception (e.g. condoms, intra-uterine device, pessary) should be used during treatment with Artemether/Lumefantrine 20mg/120mg Tablets.

It is important that your doctor or health care provider knows about all your symptoms, even when you think they are not related to malaria infection.

Other medicines and Artemether/Lumefantrine 20mg/120mg Tablets

It is important that you tell your doctor, health care provider or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription. These may affect the action of Artemether/Lumefantrine 20mg/120mg Tablets or Artemether/Lumefantrine 20mg/120mg Tablets may affect their action. Side effects of either medicine may become worse and/or the medicines may become less effective.

Especially tell your doctor or health care provider if you take or have recently taken:

- Any other medicines to treat or prevent malaria
- Medicines for your heart
- Antipsychotic medicines (for treatment of abnormal condition of the mind)
- Antidepressants (medication to alleviate mood disorders)
- Antibiotics
- Antihistamines (for treatment of, e.g., allergies)
- Cisapride (a medicine for improving gastric motility)
- Medicines to treat HIV infection
- Medicines against fungal infection
- Hormonal methods of birth control (for example birth control pills or contraceptive patch)

Artemether/Lumefantrine 20mg/120mg Tablets with food and drink

Artemether/Lumefantrine 20mg/120mg Tablets should be taken with food or a milky drink.

Pregnancy and breast-feeding

Pregnancy

Do not use this drug during pregnancy without medical advice. This is particularly important during the first 3 months of pregnancy.

Breast-feeding

Breast-feeding can be considered after medical advice.

Driving and using machines

Artemether/Lumefantrine 20mg/120mg Tablets may cause dizziness and fatigue. If you feel dizzy or fatigued while taking Artemether/Lumefantrine 20mg/120mg Tablets, do not drive, use any tools or machines.

3. HOW TO TAKE ARTEMETHER/LUMEFANTRINE 20MG/120MG TABLETS

Artemether/Lumefantrine 20mg/120mg Tablets should always be taken exactly as described by the doctor or health care provider. You should check with your doctor, health care provider or pharmacist if you are not sure.

The dose of Artemether/Lumefantrine 20mg/120mg Tablets is decided on the basis of your or your child's body weight.

Number of Artemether/Lumefantrine 20mg/120mg Tablets for treatment according to weight bands;

Weight range	Time					
	Day 1		Day 2		Day 3	
	Immediately after diagnosis/ onset of symptoms	8 hours after previous dose	12 hours after previous dose	12 hours after previous dose	12 hours after previous dose	12 hours after previous dose
from 5kg up to 15kg	1 tablet	1 tablet	1 tablet	1 tablet	1 tablet	1 tablet
From 15kg up to 25kg	2 tablets	2 tablets	2 tablets	2 tablets	2 tablets	2 tablets
From 25kg up to 35kg	3 tablets	3 tablets	3 tablets	3 tablets	3 tablets	3 tablets
From 35kg (or \geq 12 years of age)	4 tablets	4 tablets	4 tablets	4 tablets	4 tablets	4 tablets

The first dose should be followed by a second dose after 8 hours. The following two days the doses of Artemether/Lumefantrine 20mg/120mg Tablets should be taken 12 hours apart.

Artemether/Lumefantrine 20mg/120mg Tablets should be taken with food or a milky drink. If you are unable to tolerate food, Artemether/Lumefantrine 20mg/120mg Tablets should still be administered, but your body may take up less of the medicine. If you vomit within 1 hour of taking the medication, you should repeat the dose.

For very young children or patients not able to swallow the tablets whole, the tablets may be crushed and added to a small amount of semi-solid food or liquid, all of which should be consumed immediately.

If you take more Artemether/Lumefantrine 20mg/120mg Tablets than you should

If you take too many tablets, you may develop an abnormal heartbeat. Immediately contact your doctor, health care provider or the nearest hospital emergency department for further advice.

If you forget to take Artemether/Lumefantrine 20mg/120mg Tablets

Try to make sure that you do not miss any dose. However, if you do forget a dose, take the missed dose as soon as you realise that you have forgotten it. Then take the next dose after the prescribed interval. **Do not take a double dose to make up for a forgotten tablet. Make sure you take all six doses of this regimen.**

If you stop taking Artemether/Lumefantrine 20mg/120mg Tablets

You should keep taking the medicine for as long as your doctor has ordered, even if you are feeling better. If you stop the medicine too soon, the infection may not be completely cured.

If you have any further questions on the use of this product, ask your doctor, health care provider or pharmacist.

4. POSSIBLE SIDE EFFECTS

Like all medicines, Artemether/Lumefantrine 20mg/120mg Tablets can cause side effects, although not everybody gets them. When treating malaria, it is not always possible to differentiate between unwanted effects caused by Artemether/Lumefantrine 20mg/120mg Tablets and those caused by any other medicines you may be taking at the same time. For this reason, it is important that you inform the doctor or health care provider of any change in your health.

The following side effects have been reported in patients treated with Artemether/Lumefantrine 20mg/120mg Tablets:

The *most commonly* reported side effects (greater than 1 in every 10 patients treated) include headache, dizziness, feeling sick, vomiting, abdominal pain, loss of appetite, palpitations, pain in muscles and joints, fatigue and disturbed sleep.

Commonly (greater than 1 in every 100 patients treated) reported side effects include alterations to the electrocardiogram (ECG), tingling in hands and feet, problems with walking, cough, diarrhoea, itching, rash and insomnia.

Uncommon side effects (greater than 1 in every 1000 patients treated but less than 1 in 100): involuntary muscle jerks, coordination disturbances, altered liver function tests and drowsiness.

The following side effects have been reported in patients treated with Artemether/Lumefantrine 20mg/120mg Tablets. However, frequency estimates for these effects are not available: hypersensitivity reaction, hives, rapid swelling of the face and throat (angioedema).

A similar side effect profile was reported for children.

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

5. HOW TO STORE ARTEMETHER/LUMEFANTRINE 20MG/120MG TABLETS

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

Do not store above 30°C. Store tablets in the blisters in the provided carton.

Do not use Artemether/Lumefantrine 20mg/120mg Tablets after the expiry date which is stated on the blister and the outer packaging after EXP. The expiry date refers to the last day of that month.

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/Lumefantrine 20mg/120mg Tablets contains

The active ingredients are: 20 mg artemether and 120 mg lumefantrine.

The other ingredients are:

Colloidal silicon dioxide, croscarmellose sodium, hypromellose, magnesium stearate, microcrystalline cellulose and polysorbate 80.

What Artemether/Lumefantrine 20mg/120mg Tablets looks like and contents of the pack

Artemether/Lumefantrine 20mg/120mg Tablets is a yellow coloured, circular, flat bevel edged uncoated tablet with break-line on one surface and plain on other side.

The break-line is only to facilitate breaking for ease of swallowing and not to divide into equal doses.

Artemether/Lumefantrine 20mg/120mg Tablets is provided in clear transparent PVC/PE/PVDC-Alu blisters.

Five different presentations are available:

- Four blisters of 6 tablets packed in one carton
- One blister of 6 tablets packed in one carton
- One blister of 12 tablets packed in one carton
- One blister of 18 tablets packed in one carton
- One blister of 24 tablets packed in one carton

Manufacturer

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