

# **PATIENT INFORMATION LEAFLET: INFORMATION FOR THE USER**

## **LARTEM**

### **Artemether 20mg + Lumefantrine 120mg tablets**

**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 before, during or after use of this medicine.
- If you have any further questions, ask your health care provider.
- This medicine has been prescribed for you only. Do 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 become serious, or if you notice any side effects not listed in this leaflet, please inform your health care provider.

#### **In this leaflet:**

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

## **1. What Artemether 20mg + Lumefantrine 120mg tablet is and what it is used for**

Artemether 20mg + Lumefantrine 120mg tablet contain two substances called artemether and lumefantrine. They belong to a group of medicines called anti-malarials.

Artemether 20mg + Lumefantrine 120mg 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 20mg + Lumefantrine 120mg tablet is used to treat adults, children and infants of 5 kg body weight and above.

Artemether 20mg + Lumefantrine 120mg tablet 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 20mg + Lumefantrine 120mg tablets**

### **Do not take Artemether 20mg + Lumefantrine 120mg tablet:**

- If you are allergic (hypersensitive) to artemether, lumefantrine, or any of the other ingredients of Artemether 20mg + Lumefantrine 120mg tablet listed at the end of this leaflet.
- 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 heartbeat, a slow heartbeat, 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 “Taking other medicines”).
- If you are taking certain medicines (see also “Taking other medicines”). If any of the above applies to you, tell your doctor without taking Artemether 20mg + Lumefantrine 120mg tablet.

### **Take special care with Artemether 20mg + Lumefantrine 120mg tablet**

Check with your doctor or pharmacist before taking Artemether 20mg + Lumefantrine 120mg tablet:

- 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 20mg + Lumefantrine 120mg tablet.
- 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 20mg + Lumefantrine 120mg tablet.

### **Taking other medicines**

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.
- Medicines used to treat epilepsy (such as carbamazepine, phenytoin)
- 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 this medicine.

Please tell your doctor if you are taking:

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

### **Taking Artemether 20mg + Lumefantrine 120mg tablet with food and drink**

Artemether 20mg + Lumefantrine 120mg tablet 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 20mg + Lumefantrine 120mg tablet with.

### **Pregnancy and breast-feeding**

Tell your doctor if you are pregnant, think you may be pregnant or become pregnant while taking Artemether 20mg + Lumefantrine 120mg tablet.

Artemether 20mg + Lumefantrine 120mg tablet 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 20mg + Lumefantrine 120mg tablet only if clearly necessary.

Your doctor will discuss with you the potential risk of taking Artemether 20mg + Lumefantrine 120mg tablet 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 20mg + Lumefantrine 120mg tablet. Once you have stopped taking Artemether 20mg + Lumefantrine 120mg tablet, 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 20mg + Lumefantrine 120mg tablet 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 20mg + Lumefantrine 120mg tablets**

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 or giving Artemether 20mg + Lumefantrine 120mg 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 20mg + Lumefantrine 120mg 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.
- 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.

#### **Dosage and Administration:**

Artemether 20mg + Lumefantrine 120mg Tablets - 24 tablets

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

1st dosage, at the time of initial diagnosis	4 Tablets
2nd dosage, at 8 hours after 1st dose	4 Tablets
3rd dosage, at 24 hours after 1st dose	4 Tablets

4th dosage, at 36 hours after 1st dose                      4 Tablets  
 5th dosage, at 48 hours after 1st dose                      4 Tablets  
 6th dosage, at 60 hours after 1st dose                      4 Tablets

Body Weight in Kg	☀ Day 1 ☾		☀ Day 2 ☾		☀ Day 3 ☾	
	0 Hrs	8 Hrs	Morning	Night	Morning	Night
5 to < 15	●		●		●	
15 to < 25	●		●		●	
25 to < 35	●	●	●	●	●	●
Adult & children 35 kg & above	●	●	●	●	●	●

**If the malaria infection returns**

A second course of Artemether 20mg + Lumefantrine 120mg 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 20mg + Lumefantrine 120mg 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 20mg + Lumefantrine 120mg Tablets**

Try to make sure that you do not miss any doses. However, if you do forget a dose of Artemether 20mg + Lumefantrine 120mg Tablets, 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 20mg + Lumefantrine 120mg 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**

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. Some side effects could be serious and need immediate medical attention (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

#### **5. How to store Artemether 20mg + Lumefantrine 120mg tablets**

Store in a dry place below 30°C. Protect from light.

Keep this medicine out of the sight and reach

Do not take this medicine after the expiry date which is stated on the blister and carton 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 20mg + Lumefantrine 120mg tablets contains**

- The active substances are artemether and lumefantrine.
- The other ingredients are Microcrystalline Cellulose BP, Hypromellose E15 (Dry Mix) (Hydroxy Propyl Methyl Cellulose E15) BP, Polysorbate 80 BP, Maize Starch BP, Purified Water BP, Purified Talc BP, Magnesium Stearate BP, Crospovidone BP, Colloidal Anhydrous Silica BP.

##### **• What Artemether 20mg + Lumefantrine 120mg tablets looks like and contents of the pack**

Artemether 20mg + Lumefantrine 120mg tablets are Yellow coloured tablet circular uncoated flat beveled edges, having break line on one side and another side plain.

Alu/PVC-PVDC blister pack of 6's/12's/18's & 24's tablets in a carton with insert.

##### **• Supplier and Manufacturer**

**S Kant HEALTHCARE Ltd.**

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