

PATIENT INFORMATION LEAFLET: INFORMATION FOR THE USER

LARTEM FORTE

ARTEMETHER 80mg + LUMEFANTRINE 480mg TABLETS

Read all of this leaflet carefully before you start taking this medicine.

- 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 LARTEM FORTE is and what it is used for
2. What you need to know before you take LARTEM FORTE
3. How to take LARTEM FORTE
4. Possible side effects
5. How to store LARTEM FORTE
6. Contents of the pack and other information

1. WHAT LARTEM FORTE IS AND WHAT IT IS USED FOR

LARTEM FORTE Tablets a fixed dose combination of artemether and lumefantrine in the ratio of 1:6, is an antimalarial agent. LARTEM FORTE Tablets contain artemether, lumefantrine which are blood schizonticides.

Artemether is a Synthetic antimalarial derived from artemisinin. Mechanism of action, involves an interaction with ferriprotoporphyrin IX (“heme”), or ferrous ions, in the acidic parasite food vacuole, which results in the generation of cytotoxic radical species. The generally accepted mechanism of action of peroxide antimalarials involves interaction of the peroxide-containing drug with heme, a hemoglobin degradation by product, derived from proteolysis of hemoglobin. This interaction is believed to result in the formation of a range of potentially toxic oxygen and carbon-centered radicals.

Lumefantrine is a dichlorobenzylidene derivative given by mouth in combination with artemether for the treatment of uncomplicated falciparum malaria. It is a blood schizonticide with a relatively slow onset of action but it has a longer duration of action. Lumefantrine is given over a period for 60 hours in combination with artemether, administered at diagnosis. Treatment with artemisinin and its derivatives appears to be generally well tolerated, although there have been reports of mild gastrointestinal disturbance, dizziness, tinnitus, neutropenia, elevated liver enzyme values and ECG abnormalities including prolongation of the QT interval.

LARTEM FORTE is used for the treatment of severe falciparum malaria, cerebral malaria, multi-drug resistant malaria. It is indicated for the treatment of acute uncomplicated Plasmodium falciparum malaria in adult, children and infants of 5 kg and above. Consideration should be given to official guidance regarding the appropriate use of antimalarial agents.

2. BEFORE YOU TAKE LARTEM FORTE

- **Do not LARTEM FORTE**

- if you are allergic (hypersensitive) to artemether, lumefantrine, or any of the other ingredients of LARTEM FORTE 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 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 LARTEM FORTE.

- **Take special care with LARTEM FORTE**

Check with your doctor or pharmacist before taking LARTEM FORTE

- 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 LARTEM FORTE.
- 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 LARTEM FORTE.

- **Taking LARTEM FORTE with food and drink**

- LARTEM FORTE 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 LARTEM FORTE with.

- **Pregnancy and breast-feeding**

- Tell your doctor if you are pregnant, think you may be pregnant or become pregnant while taking LARTEM FORTE.
- LARTEM FORTE 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 LARTEM FORTE only if clearly necessary.
- Your doctor will discuss with you the potential risk of taking LARTEM FORTE during pregnancy.
- You should not breast-feed while you are taking LARTEM FORTE. Once you have stopped taking LARTEM FORTE, 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**

LARTEM FORTE may make you feel sleepy, dizzy or generally weak. If this happens to you, do not drive or use any tools or machines.

- **Important information about some of the ingredients of LARTEM FORTE**

None stated.

3. HOW TO TAKE LARTEM FORTE

Always take or give LARTEM FORTE exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure.

- **Taking LARTEM FORTE**

- 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 LARTEM FORTE 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.

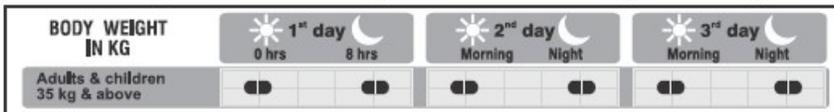
Follow your doctor s instructions carefully and use only the number of tablets needed. Return the remaining tablets to your pharmacist.

How much LARTEM FORTE to take

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

Adults and adolescents weighing 35kg and above

1st dosage, at the time of initial diagnosis	1 Tablet
2nd dosage, at 8 hours after 1st dose	1 Tablet
3rd dosage, at 24 hours after 1st dose	1 Tablet
4th dosage, at 36 hours after 1st dose	1 Tablet
5th dosage, at 48 hours after 1st dose	1 Tablet
6th dosage, at 60 hours after 1st dose	1 Tablet
Total number of tablets:	6 tablets



- **If you take more LARTEM FORTE than you should**

If you take more LARTEM FORTE 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 LARTEM FORTE**

Try to make sure that you do not miss any doses. However, if you do forget a dose of LARTEM FORTE, 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 LARTEM FORTE**

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, LARTEM FORTE 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)

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), muscle twitching, decreased skin sensitivity), sleepiness. These side effects have been reported in adults and adolescents above 12 years of age. 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 LARTEM FORTE

Keep out of the reach and sight of children.

Do not use LARTEM FORTE after the expiry date which is stated on the carton. The expiry date refers to the last day of that month.

Store in a cool and dry place not above 30°C. Protect from light.

Do not use LARTEM FORTE 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

• What LARTEM FORTE contains

The active substance(s) are as follows: Artemether Ph. Eur & Lumefantrine Ph. Eur

The other ingredient(s) are as follows: Microcrystalline Cellulose powder BP, Hydroxy Propyl methyl Cellulose E15 BP, Polysorbate 80 BP, Maize Starch, Purified water BP, Talcum BP, Magnesium Stearate BP, Crospovidone BP, Colloidal Anhydrous Silica BP

• What LARTEM FORTE looks like and contents of the pack

Yellow Coloured, circular capsule shape, uncoated biconvex table, having central break line on one side and plain on other side.

LARTEM FORTE tablets are available in blister packs containing 1 x 6 tablets.

• Supplier and Manufacturer

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