Information for the patient

Lumartem DT[1]
Artemether/Lumefantrine 20mg/120mg dispersible 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.
- If you have questions about the medicine, 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 signs of illness seem to be the same as yours.
- If you get any side effects, talk to your health care provider. This includes unwanted effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What Lumartem DT 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.
Lumartem DT 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 health care provider has found that you have malaria and so has prescribed Lumartem DT. 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 health care provider.

2. What you need to know before you takeLumartem DT

Do not take Lumartem DT:
- If you are allergic (hypersensitive) to artemether, lumefantrine, or any of the other ingredients of the Lumartem DT listed at the end of this leaflet.
- If you have a severe type of malaria infection that affects the brain, or any other severe complications of malaria (for example affecting the lungs or kidneys).
- If you have a heart condition, such as changes in the rhythm or rate of the heartbeat, e.g. called "prolongation of the QT interval", slow heartbeat, or severe cardiac disease.
- If any member of your family (e.g. parents, grandparents, brothers and sisters) has died suddenly due to a heart rate problem or is known to have been born with heart rate problems.

[1]Trade names are not prequalified by WHO. This is the National Medicines Regulatory Authority's (NMRA) responsibility. Throughout this WHOPAR the proprietary name is given as an example only.

- If you are taking certain medicines (see "Taking other medicines").
- If you have low blood levels of electrolytes such as potassium or magnesium.

If any of these apply to you**, tell your health care provider before taking Lumartem DT**.

- If you think you may be allergic, ask your health care provider for advice.

Warnings and precautions

Talk to your health care provider **before taking Lumartem DT**:

- If you have severe liver or kidney problems.

Take special care with Lumartem DT:

- If your condition worsens, or if you feel too unwell to eat and drink, contact your health care provider immediately. Your health care provider may want to perform a test called an electrocardiogram (ECG) and check the levels of electrolytes, such as potassium and magnesium in your blood before and during treatment.
- If you are taking or have taken any other medication for the treatment of malaria, talk to your health care provider, because some of these medicines must not be given together with Lumartem DT.
- If you are infected with both, *Plasmodium falciparum* and *Plasmodium vivax*, your health care provider will give you another medicine for you to take after completing Lumartem DT treatment.

Other medicines and Lumartem DT

It is important that you tell your health care provider if you are taking or have recently taken any other medicines, including medicines obtained without a prescription. These may affect the action of Lumartem DT, or Lumartem DT may affect their action. Side effects of either medicine may become worse and/or the medicines may become less effective.
Especially tell your 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 to treat hepatitis B or hepatitis C infection
- Medicines against fungal infection
- Hormonal methods of birth control (for example birth control pills or contraceptive patch)

Lumartem DT with food and drink

Lumartem DT should be taken with food or a milky drink.

Pregnancy, breast-feeding and fertility

Pregnancy
Lumartem DT can be used during pregnancy.

Breast-feeding
The actives of Lumartem DT appear in low amounts in human milk, but at therapeutic doses no effects on the breast-fed baby are anticipated.
Lumartem DT can be used during breast-feeding.

Fertility
There is no information on the effects of Lumartem DT on fertility in humans.

Driving and using machines

Lumartem DTmay cause dizziness and fatigue. If you feel dizzy or fatigued while taking Lumartem DT, do not drive and do not use any tools or machines.

3. How to takeLumartem DT

Lumartem DT should always be taken exactly as described by the health care provider. You should check with your health care provider if you are not sure.

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 ≥ 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 should be taken 12 hours apart.

Giving Lumartem DT

1. Take 2 teaspoons (10 ml) of water in a small and clean container and add the required number of tablets.
2. Swirl the container until tablet disperses, and administer the entire mixture immediately.
3. Rinse the container with an additional 10 ml of water and get the child to drink this water.

Lumartem DT should be taken with food or a milky drink. If you are unable to tolerate food, Lumartem DT should still be taken, 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.

If you take more Lumartem DT than you should

If you take too many tablets, immediately contact your health care provider or the nearest hospital emergency department for further advice.

If you forget to take Lumartem DT

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 Lumartem DT

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

Children weighing less than 5 kg

Lumartem DT is not for use in these patients.

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

4. Possible side effects

Like all medicines, Lumartem DT can cause side effects, although not everybody gets them. It is important that you inform the health care provider of any change in your health.

The following side effects have been reported in adults and adolescents above 12 years of age using the recommended 6-dose regimen. A similar side effect profile was reported for children

The *most commonly* reported side effects (greater than 1 in every 10 patients treated) include palpitations, headache, dizziness, nausea, vomiting, abdominal pain, decreased appetite, joint pain, muscle pain, weakness, tiredness, sleep disorders.

Commonly (greater than 1 in every 100 patients treated) reported side effects include cough, rash, itching, diarrhoea and involuntary, rhythmic, muscular contractions (clonus).

Uncommon side effects (greater than 1 in every 1000 patients treated but less than 1 in 100): alterations to the electrocardiogram (QT-prolongation), lack of voluntary coordination of muscle movements, which may present e.g. as gait disturbance, numbness (hypoesthesia), somnolence, urticaria, blood tests for liver function abnormal.

Allergic reactions and anaemia (low red blood cell count) have been reported in patients treated with Lumartem DT tablets. However, frequency estimates for this side effect are not available. Allergic reactions may present with rash, hives, rapid swelling of the face and throat (angioedema).

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

Reporting of side effects

If you get any side effects,talk to your health care provider. This includes unwanted effects not listed in this leaflet.If available, you can also report side effects directly through the national reporting system. By reporting side effects, you can help provide more information on the safety of this medicine.

5. How to store Lumartem DT

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

Do not use this medicine after the expiry date stated on the blister pack and carton after EXP.
The expiry date refers to the last day of that month.

Do not throw away any medicines in waste water or household waste. Ask your health care provider how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

Lumartem DT is packed in PVC/Aclar/PVC-Alu blister packs.

Pack size: Carton containing a blister of 6 tablets.
Carton containing a blister of 12 tablets.

Carton containing 30 blisters of 6 tablets each.
Carton containing 30 blisters of 12 tablets each.

What Lumartem DT contains

The active substances are artemether and lumefantrine.

The other ingredient(s) in Lumartem DT are:
Microcrystalline cellulose*;* croscarmellose sodium*;* crospovidone*;* hydroxypropyl methylcellulose*;* polysorbate 80*;* colloidal anhydrous silica*;* saccharin sodium*;* cherry flavour permaseal (11035-31) and magnesium stearate

What Lumartem DT looks like and contents of the pack

Lumartem DT is a yellow coloured, circular shaped, flat bevelled, uncoated tablets, debossed with 'CL' on one side and plain on the other side.
No score line.

Supplier
Cipla Ltd
Cipla House
Peninsula Business Park
Ganpatrao Kadam Marg
Lower Parel
Mumbai: 400013
India
Tel: +91 22 24826000

Manufacturer
CiplaLimited
Unit IV, Plot no. 9 & 10
Pharma Zone, Phase II
Indore special economic zone
Pithampur (MP) – 454775
India

For any information about this medicine, contact the supplier:

This leaflet was last revised in March 2018

Detailed information on this medicine is available on the World Health Organization (WHO) web site:
https://extranet.who.int/prequal/