# Information for the patient Lumet HS 80<sup>†</sup>

### Lumet HS 80

Artemether/Lumefantrine 80 mg/480 mg 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
- 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 vours.
- If you are concerned about any side effects, talk to your health care provider. This includes unwanted effects not listed in this leaflet. See

What is in this leaflet

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Lumet HS 80

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- What Lumet HS 80 is and what it is used for 2. What you need to know before you take Lumet HS 80
- 3. How to take Lumet HS 80
- 4. Possible side effects
- . How to store Lumet HS 80 6. Contents of the pack and other information

1. What Lumet HS 80 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 35 kg or more. Lumet HS 80 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 Lumet HS 80. It is indicated only for the treatment of so called uncomplicated malarial attacks due to *Plasmodium falciparum* (a particular type of malaria parasite).

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 take Lumet HS 80 Do not take Lumet HS 80:

- If you are allergic (hypersensitive) to artemether, lumefantrine, or any of the other ingredients of the Lumet HS 80 listed at the end of this
- 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.
- If you are taking certain medicines (see "Taking other medicines"). If you have low blood levels of electrolytes such as potassium or

# If any of these apply to you, tell your health care provider before taking

 $^\dagger\textsc{Trade}$  names are not prequalified by WHO. This is the national medicines regulatory agency's responsibility.

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

Warnings and precautions Talk to your health care provider **before taking Lumet HS 80**:

- If you have severe liver or kidney problems.

# Take special care with Lumet HS 80:

- 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 Lumet HS 80. 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 Lumet HS 80 treatment.

### Other medicines and Lumet HS 80

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 Lumet HS 80, or Lumet HS 80 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)

# Lumet HS 80 with food and drink Lumet HS 80 should be taken with food or a milky drink.

#### Pregnancy, breast-feeding and fertility Pregnancy

During the first three months of pregnancy use Lumet HS 80 only with medical advice. Later in pregnancy Lumet HS 80 can be used. Breast-feeding

The actives of Lumet HS 80 appear in low amounts in human milk, but at therapeutic doses no effects on the breast-fed baby are anticipated. Lumet HS 80 can be used during breast-feeding.

### Fertility There is no information on the effects of Lumet HS 80 on fertility in

## humans.

#### Driving and using machines Lumet HS 80 may cause dizziness and fatigue. If you feel dizzy or tired

#### while taking Lumet HS 80, do not drive and do not use any tools or machines.

3. How to take Lumet HS 80

Lumet HS 80 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.

Take one tablet of Lumet HS 80 twice a day for three days (total six doses).

Take the first dose immediately when your health care provider has diagnosed malaria. Take the second dose 8 hours after the first dose. Take the following doses 12 hours apart.

Lumet HS 80 should be taken with food or a milky drink. If you are unable to tolerate food, Lumet HS 80 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 Lumet HS 80 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 Lumet HS 80

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.

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If you stop taking Lumet HS 80 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.

atients weighing less than 35 kg. Lumet HS 80 is not for use in patients weighing less than 35 kg. Other

formulations containing lower amounts of artemether/lumefantrine are available for these patients. If you have any further questions on the use of this product, ask your

# 4. Possible side effects

Like all medicines, Lumet HS 80 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. 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 could be serious and need immediate medical

Rare (may affect up to 1 in 1,000 people): 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: The most commonly reported side effects (greater than 1 in every 10 patients treated) include fast heart beat (palpitations), headache, dizziness, nausea, vomiting, abdominal pain, decreased appetite, joint pain, muscle pain, general weakness, tiredness, sleep disorders.

 $\textit{Commonly} \ (\textit{greater than} \ 1 \ \textit{in every} \ 100 \ \textit{patients treated}) \ \textit{reported side}$ effects include alterations to the electrocardiogram (QT-prolongation), abnormal blood tests for liver function, rash, itching, diarrhoea, abnormal walking\*, needles and pins (paraesthesia) or numbness of the hands and feet\*, involuntary, rhythmic, muscular contractions (clonus), insomnia.

Uncommon side effects (greater than 1 in every 1000 patients treated but less than 1 in 100) include lack of voluntary coordination of muscle movements (ataxia)\*, decreased skin sensitivity\*, somnolence, itching rash (such as urticaria).

\*These side effects have been reported in adults and adolescents above

Not known (frequency cannot be estimated from the available data): anaemia due to breakdown of red blood cells, which has been reported

up to a few weeks after treatment has been stopped (delayed haemolytic 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

Reporting of side effects

12 years of age.

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 improve understanding about the safety of this

# 5. How to store Lumet HS 80

Lumet HS 80 should be stored below 30°C, protected from light. Keep this medicine out of the reach and sight of children.

Do not use this medicine after the expiry date which is stated on the carton after "EXP". The expiry date refers to the last day of that month. Do not throw away any medicines in wastewater 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 What Lumet HS 80

contains The active substances are artemether and lumefantrine. Each tablet

contains 80 mg artemether and 480 mg lumefantrine.

The other ingredients of Lumet HS 80 are: microcrystalline cellulose; croscarmellose sodium; hypromellose; polysorbate 80; colloidal anhydrous silica; and magnesium stearate.

What Lumet HS 80 looks like and contents of the pack

Lumet HS 80 is a yellow-coloured, capsule-shaped, biconvex uncoated tablet, debossed with '80' on one side and a scoreline on the other side. The score-line is only to facilitate breaking for ease of swallowing and not to divide into equal doses. Lumet HS 80 is packed in PVC/Aclar/PVC-Alu

Pack size: Carton containing a blister of 6 tablets.

Supplier and Manufacturer CiplaQCIL Plot 1-7, 1st Ring Road, Luzira Industrial Park, Village Upper Malpur P.O. Bhud. Tehsil Nalagarh District Solan Himachal Pradesh P.O. Box 34871, Kampala, Uganda Phone: +256-312341100/65 E-mail: info@ciplaqcil.co.ug

Website: www.ciplaqcil.co.ug For any information about this medicine, contact the supplier This leaflet was last revised in May 2021

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