NOVARTIS

COARTEM®

(Artemether/Lumefantrine)

20 mg/120 mg, tablets

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COARTEM® 20 mg/120 mg tablets

artemether/lumefantrine

Sugar-free

Read all of this leaflet carefully before you start taking COARTEM

- Keep this leaflet. You may need to read it again.
- If you have any further questions, please ask your doctor, pharmacist, nurse or other health care provider.
- COARTEM has been prescribed for you personally and you should not share your medicine with other people. It may harm them, even if their symptoms are the same as yours.

What is in this leaflet

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

1. What COARTEM is and what it is used for

COARTEM is a fixed combination of the two active substances artemether and lumefantrine. Each COARTEM tablet contains 20 mg of artemether and 120 mg of lumefantrine as well as: croscarmellose sodium, hydroxypropyl methylcellulose, magnesium stearate, microcrystalline cellulose, polysorbate 80 and silica colloidal anhydrous.

WHAT COARTEM IS USED FOR

COARTEM belongs to the group of medicines known as antimalarials, i.e. medicines used to treat certain types of malaria infections. It destroys the malaria parasites (tiny organisms consisting of a single cell that are found inside the red blood cells).

COARTEM is used to treat adults, infants and children with malaria infections caused by *Plasmodium falciparum* (a particular type of malaria parasite) or with mixed infections that include *Plasmodium falciparum*.

COARTEM is not suitable for preventing malaria, nor for treating severe malaria (e.g. affecting your brain, kidneys, or lungs).

2. What you need to know before you take COARTEM Do not take COARTEM

- If you are allergic (hypersensitive) to artemether, lumefantrine, or any of the other ingredients of the COARTEM tablets listed at the end of this leaflet.
- If you think you may be allergic, ask your doctor for advice.
- 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 are in the first 3 months of pregnancy or intend to become pregnant and it is possible for the doctor to give you an alternative medicine.
- If you are breastfeeding your baby. If you have a heart condition, such as changes in the rhythm or rate of the heartbeat, 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 be born with heart rate problems.
- If you are being treated with medicines that affect the heartbeat (known as anti arrhythmics) (see “Other medicines and COARTEM”).
- If you have low blood levels of electrolytes such as potassium or magnesium.

If any of these apply to you, tell your doctor before taking COARTEM

Warnings and precautions

- 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 *Plasmodium falciparum* and *Plasmodium vivax* your doctor will prescribe another medicine for you to take after completing COARTEM treatment.
- If your condition worsens, or if you feel too unwell to eat and drink, contact your doctor immediately. Your doctor 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 doctor, because some of these medicines must not be given together with COARTEM.

Children and adolescents
COARTEM is suitable for use in children who weigh 5 kg or more. Specific dosage recommendations can be found in the section “How to take COARTEM”.

Older people
No special precautions or dosage adjustments are considered to be necessary.

Other medicines and COARTEM
Always tell your health care provider if you are taking any other medicine. (This includes all complementary or traditional medicines).

Some medicines must not be taken with COARTEM. These include:

- certain medicines used for the treatment of heart rhythm disturbances (e.g. flecainide, metoprolol),
- certain medicines used to treat depression (e.g. imipramine, amitriptyline, clomipramine),
- certain types of medicines to treat infections such as:
    - antibiotics, including medicines of the following classes: macrolides, fluoroquinolones, imidazole
    - triazole antifungal agents
- certain medicines used for the treatment of allergies or inflammation (non-sedating antihistaminics, e.g. astemizole),

- a medicine used to treat stomach disorders: cisapride,
- certain medicines used to treat epilepsy (such as carbamazepine, phenytoin),
- St John's wort (Hypericum perforatum) a medicinal plant or extract of this medicinal plant used to treat for example depressed mood.

Tell your doctor if you have recently taken any other:

- medicines used for the treatment of malaria.
- any anti-retroviral medicines or protease inhibitor (used to treat HIV infections or AIDS).
- hormonal birth control medicine (in this case you should follow an additional method of birth control).

COARTEM with food and drink

COARTEM should be taken with food or drinks rich in fat (e.g. milk). Consumption of 30–60 g of fat per day or breast milk is adequate for this purpose. Grapefruit juice should be avoided.

Pregnancy

If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist or other health care provider for advice before taking this medicine. COARTEM must not be used during the first 3 months of pregnancy. Your doctor should prescribe an alternative antimalarial medicine to you as there are potential serious consequences for the foetus if you continue treatment with COARTEM.

Breastfeeding

You should not breastfeed your infant while you are taking COARTEM. Once you have stopped taking COARTEM, you should not start breastfeeding again until at least 4 weeks after taking the last tablet.

Women of childbearing potential

Women who are capable of becoming pregnant are advised to use an effective method of contraception while on COARTEM treatment, and until the start of the next menstruation

after treatment. If you are taking hormonal birth control medicine, you should also use an additional method of birth control.

Driving and using machines
COARTEM may make you feel sleepy, dizzy or generally weak. If this happens to you, do not drive or use machines.

It is not always possible to predict to what extent COARTEM may interfere with the daily activities of a patient. Patients should ensure that they do not engage in the above activities until they are aware of the measure to which COARTEM affects them.

3. How to take COARTEM

Do not share medicines prescribed for you with any other person.

Always take COARTEM exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

The tablets should be taken with food or drinks rich in fat (e.g. milk). Consumption of 30–60 g of fat per day or breast milk is adequate for this purpose. If you are too unwell to eat or drink, you should still take COARTEM as prescribed and contact your doctor.

How many COARTEM to take:
A six-dose regimen over 3 days is recommended, as described below.

Adults and adolescents weighing 35 kg and above:

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

Infants and children weighing 5 kg to less than 35 kg:

Dose/time	**Body weight 5 kg to less than 15 kg**	**Body weight 15 kg to less than 25 kg**	**Body weight 25 kg to less than 35 kg**
1st dose, at the time of initial diagnosis	1 tablet	2 tablets	3 tablets
2nd dose, at 8 hours after 1st dose	1 tablet	2 tablets	3 tablets
3rd dose, at 24 hours after 1st dose	1 tablet	2 tablets	3 tablets
4th dose, at 36 hours after 1st dose	1 tablet	2 tablets	3 tablets
5th dose, at 48 hours after 1st dose	1 tablet	2 tablets	3 tablets
6th dose, at 60 hours after 1st dose	1 tablet	2 tablets	3 tablets
Total number of tablets:	6 tablets	12 tablets	18 tablets
To benefit from the full therapeutic effect, the full course of medication (i.e. all 6, 12, 18 or 24 tablets) must be taken over the 60 hours at intervals as indicated.			

- For administration to small children and infants, the tablet(s) may be crushed. Follow carefully the dosage prescribed by the doctor and use only the number of tablets needed. Return the remaining tablets to your pharmacist.
- If you vomit within one hour of taking the tablets, contact your doctor or pharmacist immediately, you may need to take another dose.

- Usually the tablets should be taken with fluids (e.g. milk) and some food. If you are too unwell to eat, you should still take COARTEM as prescribed and contact your doctor.

If you take more COARTEM than you should

In the event of overdosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison centre.

If you forget to take COARTEM

Do not take a double dose to make up for forgotten individual doses.

What else should you be aware of while taking COARTEM?

A second course of COARTEM may be necessary if the malaria infection returns (relapse) or if you are re-infected with *Plasmodium falciparum* after having been cured.

4. Possible side effects

COARTEM can have side effects.

Not all side effects reported for COARTEM are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking COARTEM, please consult your doctor, pharmacist or other health care provider for advice.

The following side effects could be serious

This side effect is rare, it may affect up to 1 in every 1,000 people

- Allergic reaction (may include rash, itching, swelling mainly of the face or throat, difficulty breathing or swallowing, or dizziness).

This side effect is uncommon, it may affect up to 1 in every 100 people

- Heart rhythm disturbances (called QTc prolongation or abnormal ECG heart tracing).

If you experience any serious side effects, stop taking this medicine and tell your doctor immediately.

The following side effects are very common

These side effects may affect more than 1 in every 10 people

- Loss of appetite,
- Trouble with sleeping,
- Headache,
- Dizziness,
- Fast heartbeat,
- Cough,
- Stomach pain,
- Nausea (feeling sick) and / or vomiting,
- Aching joints and muscles,
- Tiredness and general weakness.

The following side effects are common

These side effects may affect up to 1 in every 10 people

- Involuntary muscle contractions (sometimes in rapid spasms),
- Diarrhoea,
- Itching on the skin or a rash,
- Symptoms such as unexplained persistent nausea, stomach problems, loss of appetite or unusual tiredness or weakness (signs of liver problems).

The following side effects are uncommon

These side effects may affect up to 1 in every 100 people

- Sleepiness,
- Itching rash.

The following uncommon side effects have only been reported in adults:

- Decreased feeling or sensitivity (especially skin),
- Inability to coordinate movements,
- Abnormal walk.

If any of these side effects affects you, tell your doctor.

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

Reporting of side effects
If you get side effects, talk to your doctor, pharmacist or nurse. You can also report side effects to SAHPRA via the Med Safety APP (Medsafety X SAHPRA) and eReporting platform (who-umc.org) found on SAHPRA website. By reporting side effects, you can help provide more information on the safety of COARTEM.

5. How to store COARTEM

Store all medicines out of reach of children.

Keep your tablets in their original packaging and do not store them above 30 °C.

Keep the blisters in the outer carton until required for use, to protect the tablets from moisture. The expiry date for these tablets is printed on the outer carton. Do not take the tablets after this date.

Return all unused medicine to your pharmacist.

Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

6. Contents of the pack and other information

What COARTEM contains

- The active substances are artemether and lumefantrine
- The other ingredients are croscarmellose sodium, hydroxypropyl methylcellulose, magnesium stearate, microcrystalline cellulose, polysorbate 80 and silica colloidal anhydrous.

What COARTEM looks like and contents of the pack
Yellow, round and flat tablet with bevelled edges and score on one side. Debossed: one side “N/C” other side “CG”.

PVC/PE/PVDC blisters containing tablets in packs of 24 tablets.

Holder of Certificate of Registration

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