



PATIENT INFORMATION LEAFLET: INFORMATION FOR THE USER
ARTHEMED TABLET 80/480mg

Read this leaflet carefully before you start taking this medicine:

- 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 is Arthemed Tablet 80/480mg and what is it used for?
2. What you need to know before you use Arthemed Tablet 80/480mg
3. How to use Arthemed Tablet 80/480mg
4. Possible side effects
5. How to store Arthemed Tablet 80/480mg
6. Contents of the pack and other information

1. WHAT IS ARTHEMED TABLET 80/480mg AND WHAT IT IS USED FOR

Arthemed Tablet combination is a fixed dose artemisinin-based combination therapy (ACT) combining Artemether, an artemisinin derivative, and Lumefantrine, a synthetic antimalarial drug.

Artemether is the most active of the artemisinin, a new class of antimalarial drugs derived from artemisinin. Lumefantrine is a synthetic aryl amino alcohol similar to mefloquine and halofantrine.

2. WHAT YOU NEED TO KNOW BEFORE YOU USE ARTHEMED TABLET 80/480mg, Do not take Arthemed tablet 80/480mg

- If you are allergic (hypersensitive) to artemether, lumefantrine, or any of the other ingredients of this medicine (listed in section 6).
- 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 “other medicines and arthemed tablet 80/480mg”).
- If you are taking certain medicines (see also “other medicines and arthemed tablet 80/480mg”). If any of the above apply to you, tell your doctor without taking arthemed tablet 80/480mg.



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Warnings and precautions

Talk to your doctor or pharmacist before taking Arthemed tablet 80/480mg:

- 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 arthemed tablet 80/480mg.
- 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 arthemed tablet 80/480mg.

Other medicines and Arthemed tablet 80/480mg

Tell your doctor or pharmacist if you are taking, have recently taken or might take 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.
- 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.
- If you are taking any of the above medicines, do not take arthemed tablet 80/480mg.

Please tell your doctor if you are taking:

- Any other medicines to treat malaria.
- Medicines to treat hiv infections or aids
- An hormonal birth control medicine (in this case you should follow another method of birth control).

Arthemed Tablet 80/480mg with food and drink

Arthemed Tablet 80/480mg 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 Arthemed Tablet 80/480mg with.



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Pregnancy and breast-feeding

Arthemed Tablet 80/480mg is not recommended 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 Arthemed Tablet 80/480mg if your doctor considers it appropriate for you. Your doctor will discuss with you the potential risk of taking Arthemed Tablet 80/480mg during pregnancy.

If you are taking hormonal birth control medicine, you should also use another method of birth control for about one month.

You should not breast-feed while you are taking Arthemed Tablet 80/480mg. Once you have stopped taking Arthemed Tablet 80/480mg, you should wait at least 1 week before starting to breast-feed again.

Driving and using machines

Arthemed Tablet 80/480mg 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 USE ARTHEMED TABLET 80/480mg

Taking Arthemed Tablet 80/480mg

- 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 arthemed tablet 80/480 mg 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.

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.

Adults and children weighing 35 kg and above

Take four tablets at each time interval.

So, you take or give:

- 1 tablets as soon as possible, then
- 1 tablets 8 hours later, then
- 1 tablets 24 hours after the first dose, then



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- 1 tablets 36 hours after the first dose, then
- 1 tablets 48 hours after the first dose and then
- The final 1 tablets 60 hours after the first dose.

This will mean you take or give a total of 6 tablets.

No special precautions or dosage adjustments are necessary in elderly patients.

If the malaria infection returns

A second course of Arthemed Tablet 80/480mg 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 Arthemed 80/480mg 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 Arthemed Tablet 80/480mg

Try to make sure that you do not miss any doses. However, if you do forget a dose of Arthemed 80/480mg, 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 Arthemed Tablet 80/480mg 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 medicine, ask your doctor or pharmacist.

4. POSSIBLE SIDE EFFECTS

Like all medicines, this medicine 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 (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:

Very common (may affect more than 1 in 10 people) Fast heartbeat, headache,



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dizziness, cough, being sick (vomiting), stomach pain, feeling sick (nausea), joints or muscles aching, loss of appetite, general weakness, tiredness, trouble with sleeping.

Common (may affect up to 1 in 10 people) Involuntary muscle contractions (sometimes in rapid spasms), 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 (may affect up to 1 in 100 patients) inability to coordinate movements | , decreased skin sensitivity | , sleepiness, itching rash. |
These side effects have been reported in adults and adolescents above 12 years of age.

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 anaemia). |
These side effects have been reported in adults and adolescents above 12 years of age.

Reporting of side effects If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet.

5. HOW TO STORE ARTHEMED TABLET 80/480mg

- Keep this medicine out of the sight and reach of children.
- Do not use Arthemed Tablet 80/480mg after the expiry date which is stated on the carton. The expiry date refers to the last day of that month.
- Store below 30°C.
- Do not use Arthemed Tablet 80/480mg if you notice that the pack is damaged or shows signs of tampering.
- 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. FURTHER INFORMATION.

Each film coated tablet contains an active substance Artemether and Lumefantrine
The other ingredients are polysorbate 80, hypromellose, microcrystalline cellulose, colloidal anhydrous silica, croscarmellose sodium, and magnesium stearate.

What ARTHEMED TABLET 80/480mg looks like and contents of the pack

6 tablets is packed in Alu-PVC blister and enclosed in an inner carton with insert.



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SUPPLIER AND MANUFACTURER

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