



COMALATHER

Tablet

Composition

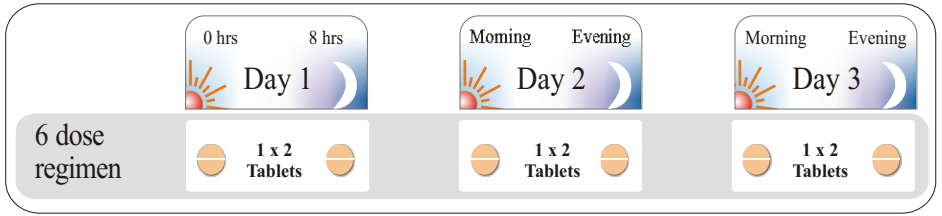
Each tablet contains Artemether 80 mg + Lumefantrine 480 mg

Indications

Co-Malather tablets are indicated for the treatment of uncomplicated *P. falciparum* malaria cases resistant to both chloroquine and sulphadoxine pyrimethamine combination.

Dosage and Administration

- Co-Malather tablets should be taken with high fat food or drinks such as milk.
- Adult and children > 35 kgs.



Clinical Pharmacology

- Artemether & lumefantrine combination is a fixed dose artemisinin-based combination therapy (ACT) combining artemether, an artemisinin derivative, and lumefantrine, a synthetic antimalarial drug.
- Both artemether and lumefantrine act as blood schizontocides. The site of antiparasitic action of both components of the combination is the food vacuole of the malarial parasite, where they are thought to interfere with the conversion of haem, a toxic intermediate produced during haemoglobin breakdown, to the non-toxic haemozoin, malaria pigment.
- Artemether is absorbed fairly rapidly with peak plasma concentrations reached about 2-3 hours after oral dosing. Absorption of lumefantrine, a highly lipophilic compound, starts after a lag period of up to 2 hrs, with peak plasma concentration about 6-8 hrs after dosing.
- Food enhances the absorption of both artemether and lumefantrine. The relative bioavailability of artemether was increased more than two fold and that of lumefantrine sixteen fold compared with fasted conditions when artemether and lumefantrine tablets were taken after a high fat meal.
- **Rationale for the combination of artemether and lumefantrine** - According to the WHO malaria treatment guidelines, uncomplicated falciparum malaria must be treated with ACT and not by artemisinin alone or any other monotherapy.
- Artemether is fast acting drug with a short half-life. Lumefantrine acts slowly and has a longer half-life. Artemether rapidly reduces parasite biomass and quickly resolves clinical symptoms, whilst the long-acting activity of lumefantrine is thought to prevent recrudescence. This dual effect also appears to reduce the selective pressure on the parasite to develop resistance.
- The antimalarial activity of the combination of lumefantrine and artemether is greater than that of either substance alone.



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Contraindications

- Hypersensitivity to the active substances or any of the excipients.

Drug Interactions:

Lumefantrine was found to inhibit CYP2D6 in vitro. This may be of particular clinical relevance for compounds with a low therapeutic index. Co-administration of artemether and lumefantrine tablets with drugs that are metabolized by this iso-enzyme (e.g. neuroleptics and tricyclic antidepressants) is contraindicated.

Precautions and Warnings

- Use with caution in patients with severe hepatic or renal insufficiency and patients refusing food intake. Patients who remain averse to food during treatment should be closely monitored as the risk of recrudescence may be greater.
- Effects on ability to drive and use machines - Driving and use of machinery is not recommended due to risk of dizziness and fatigue/asthenia.
- Usage in Pregnancy and Lactation - Co-Malather tablets are contraindicated during the first trimester of pregnancy. During the second and third trimester, treatment should only be considered if the expected benefit to the mother outweighs the risk to the foetus.
- Breast-feeding women should not take Co-Malather tablets. Due to the long elimination half-life of lumefantrine (4 to 6 days), it is recommended that breast-feeding should not resume before day 28 after discontinuation of artemether and lumefantrine combination unless potential benefits to mother and child outweigh the risk of the combination treatment.

Adverse Effects

- Common adverse events reported with artemether and lumefantrine combination included headache, dizziness, sleep disorder, abdominal pain, anorexia, diarrhoea, vomiting, nausea, palpitation, cough, arthralgia, myalgia, pruritus, rash, asthenia and fatigue.
- Somnolence, involuntary muscle contractions, paraesthesia, hypoaesthesia, abnormal gait, ataxia were other adverse effects reported with artemether and lumefantrine combination. Rare adverse event included hypersensitivity.

Overdosage

- In cases of suspected overdose, symptomatic and supportive therapy should be given as appropriate.
- ECG and blood potassium levels should be monitored.

Presentation

Co-Malather

Pack of 6 tablets

