®

ULTIMAR FORTE TABLETS

(Artemether 80mg + Lumefantrine 480 mg Tablets)

COMPOSITION:

Each tablet contains**:**

Artemether …80 mg

Lumefantrine …480 mg

Excipients …q.s.

INDICATIONS:

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ULTIMAR FORTE Tablets is indicated for the treatment of malaria caused by mixed, uncomplicated or multidrug resistant strains of P.Falciparum.

DOSAGE AND ADMINISTRATION:

Body weight/kg	**Day 1**		**Day 2**		**Day 3**	
	0 Hours	**8 Hours**	**24 Hours**	**36 Hours**	**48 Hours**	**60 Hours**
Adults & children 35 kg and above or above 12 years	1tablet	1 tablet	1tablet	1tablet	1tablet	1tablet

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ULTIMAR FORTE Tablets should be taken with food or drinks rich in fat such as milk as this improves absorption of the drugs. Repeat dose if vomiting occurs within 1 hour of administration. Eating of food should be encouraged in patients as this improves absorption of Ultimar Forte.

PHARMACOLOGICAL PROPERTIES:

PHARMACOKINETICS: Artemether administered orally is absorbed rapidly reaching therapeutic levels within 60-90 minutes. Peak plasma concentration is achieved in about 2 hours after dosing.Artemether is rapidly and extensively metabolised in the liver to the biologically active main metabolite dihydroartemisinin.Artemether and dihydroartemisinin are bound to human plasma protein and this binding is linear.The elimination of artemether and dihydroartemisinin from plasma is rapid with an elimination half-life of about 2 hours.

Lumefantrine (a highly lipophilic compound) absorption starts after a lag-time of about 2 hours with peak plasma concentration in about 6 to 8 hours after administration.Lumefantrine is eliminated very slowly with a terminal half-life of 2 to 3 days in healthy individuals and 4 to 6 days in patients with falciparum malaria.

Food enhances the absorption of both artemether and lumefantrine therefore patients are encouraged to take the medication with fatty food if possible.

PHARMACODYNAMICS: ULTIMAR FORTE tablets act as blood schizontocides and are associated with more rapid gametocyte clearance. Its site of antiparasitic effect is the food vacuole of the malaria parasite, where it is thought to interfere with the conversion of haem, a toxic intermediate produced during haemoglobin breakdown, to the non-toxic haemozin malaria pigment.

Lumefantrine is thought to interfere with the polymerisation process, while artemether generates reactive metabolites as a result of the interaction between its peroxide bridge and haem iron.Ultimar Forte has a secondary action involving inhibition of nucleic acid and protein synthesis within the malaria parasite. Data from in-vitro and in-vivo studies show that Ultimar Forte did not induce resistance.

CONTRAINDICATIONS:
Ultimar Forte is contraindicated in:
- Hypersensitivity to artemether, lumefantrine or to any of the excipients of Ultimar Forte
- Patients with severe malaria according to WHO definition
- First trimester of pregnancy in situations where other effective anti-malarias are available. It should, however, not be withheld in life –threatening situations where no other effective anti-malarials are available. During the second and third trimester, treatment should only be considered if expected benefit to the mother outweighs the risk to the foetus. Breast feeding women should not take Ultimar Forte. 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 unless potential benefits to mother and child outweighs the risks of Ultimar Forte treatment.
- Patients with known disturbances of electrolyte balance e.g. hypokalaemia or hypomagnesaemia
- Patients taking any drug which is metabolised by the cytochrome enzyme CYP2D6 e.g. flecainide, metoprolol, imipramine, amitriptyline, clomipramine
- Patients taking drugs that are known to prolong the QTC interval such as ; antiarrhythmics of Classes 1A and 111, neuroleptics and antidepressant agents, certain antibiotics, macrolides, fluoroquinolones, imidazole, triazole antifungal agents, cisapride and certain non-sedating antihistamines (terfenadine,astemizole)

DRUG INTERACTIONS:
Ultimar Forte interactions with other drugs are minimal in view of its short duration of administration and wide therapeutic index. No particular detrimental drug-drug interaction was noticed. Patients should be encouraged to eat at dosing times. Since grapefruit juice inhibits metabolism of some antimalarials it is advisable not to take it while taking ultimar forte.

SIDE EFFECTS/ADVERSE REACTIONS:
Ultimar Forte is well tolerated by infants, children and adults. Most of the reported events were of mild to moderate severity and duration and likely related to the underlying malaria or to an unsatisfactory response to the treatment rather than to ultimar forte.
Common side effects which may occur include: dizziness, anorexia, sleep disorders, headache, palpitation, vomiting, abdominal pain, nausea, arthralgia, myalgia, asthenia, fatigue.

PRECAUTIONS/WARNINGS:
Ultimar Forte is not recommended for prophylaxis. Patients who remain averse to food during treatment should be closely monitored as the risk of recrudescence may be greater. Driving and use of machinery is not recommended due to risk of dizziness and fatigue.

STORAGE:
Store in a cool, dry place below 30ºC. Ultimar Forte should not be used after the date marked "EXP" on the pack.
Keep out of reach and sight of children.