Arenax Plus®

Artemether 20 mg + Lumefantrine 120 mg

COMPOSITION

Each uncoated tablet contains:
Artemether Int. Ph. - 20 mg
Lumefantrine Int. Ph. - 120 mg

INDICATIONS

Arenax Plus® is a fixed combination of artemether and lumefantrine which acts as a blood schizonticide. It is indicated for treatment of adults and children with acute, uncomplicated infections due to *Plasmodium falciparum* or mixed infections including *P. falciparum.* It is effective against drug sensitive and drug-resistant strains of *P. falciparum.* It is also recommended for malaria infection acquired in areas where the parasites may be resistant to other antimalarials.

DOSAGE AND ADMINISTRATION

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

1. **Body weight 5 kg to less than 15 kg.**
   Day 1: 1 tablet at the time of initial diagnosis,
   and then 1 tablet after 8 hours.
   Day 2: 1 tablet in the morning and 1 tablet at night.
   Day 3: 1 tablet in the morning and 1 tablet at night.

2. **Body weight 15 kg to less than 25 kg.**
   Day 1: 2 tablets at the time of initial diagnosis,
   and then 2 tablets after 8 hours.
   Day 2: 2 tablets in the morning and 2 tablets at night.
   Day 3: 2 tablets in the morning and 2 tablets at night.

3. **Body weight 25 kg to less than 35 kg.**
   Day 1: 3 tablets at the time of initial diagnosis,
   and then 3 tablets after 8 hours.
   Day 2: 3 tablets in the morning and 3 tablets at night.
   Day 3: 3 tablets in the morning and 3 tablets at night.

4. **Adults and adolescents weighing 35 kg and above.**
   Day 1: 4 tablets at the time of initial diagnosis, then
   4 tablets after 8 hours.
   Day 2: 4 tablets in the morning and 4 tablets at night.
   Day 3: 4 tablets in the morning and 4 tablets at night.

CONTRAINDICATIONS

Arenax Plus® is contraindicated in patients with hypersensitivity to the active substances or to any of the excipients. Patients with a family history of congenital prolongation of the QTC interval or sudden death or with any other clinical condition known to prolong the QTC interval such as patients with a history of systematic cardiac arrhythmias, with clinically relevant bradycardia or with severe cardiac disease. 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 IA and III, neuroleptics, antidepressive agents, certain antibiotics including some agents of the following classes: macrolides, fluoroquinolones, imidazole and triazole antifungal agents, certain non-sedating antihistamines (terfenadine, astemizole), cisapride.

SPECIAL WARNINGS AND PRECAUTIONS

Arenax Plus® has not been evaluated for prophylaxis and is therefore not indicated.
Arenax Plus® has not been evaluated for the treatment of cerebral malaria or other severe manifestations of complicated malaria including pulmonary oedema or renal failure.
Arenax Plus® is not indicated for, and has not been evaluated in the treatment of malaria due to *P.vivax*, *P.malariae* or *P. ovale*, although some patients in clinical studies have co-infection with *P. falciparum* and *P. vivax* at baseline.
Arenax Plus® is active against blood stages of *Plasmodium vivax,* but is not active against hypnozocites. Therefore, sequential treatment with primaquine should be used to achieve hypnozoite eradication in cases of co-infection with *Plasmodium vivax.*
Patients who remain averse to food during treatment should be closely monitored as the risk of recrudescence may be greater.

PREGNANCY AND LACTATION

Pregnancy
The safe use of artemether and lumefantrine during pregnacy has not been established.
Reproductive toxicity studies in rats and rabbits have shown no evidence of teratogenicity for the combination or for the individual components, lumefantrine and artemether though artemisinins are known to be embryotoxic in animals.
Arenax Plus® was not embryotoxic in rats at doses of ≤ 25 mg/kg; however artemether alone showed materno-feto and embryotoxicity at doses ≥ 10 mg/kg in rats and ≥ 30 mg/kg in rabbits. Arenax Plus® treatment should only be considered if the expected benefit to the mother outweighs the risk to the foetus.

Lactation
Animal data suggest excretion into breast milk but no data are available in humans. Breast-feeding women should not take Arenax Plus® 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 outweigh the risk of Arenax Plus® treatment.

EFFECTS ON ABILITY TO DRIVE AND USE MACHINES
Patients receiving Arenax Plus® should be warned that dizziness or fatigue/asthenia might occur in which case they should not drive or use machines.

UNDESIRABLE EFFECTS
The frequency of adverse events reported during clinical trials with Arenax Plus® was similar to or lower than that of other antimalarial drugs as comparators.
Arenax Plus® was generally very well tolerated by children and adults, with most adverse events being of mild to moderate severity and duration. Many of the reported events are likely to be related to the underlying malaria and/or to an unsatisfactory response to the treatment rather than to Arenax Plus®

For other reports alternative factors were identified as the more likely cause of the events (e.g. concomitant infections)

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

STORAGE
Store below 30°C.
Protect from moisture and light.
Keep out of reach of children.

INSTRUCTIONS FOR USE AND HANDLING
Arenax Plus® should be kept out of the reach of children.

Packs:
1 x 6's, 2 x 6's, 3 x 6's, 4 x 6's

Manufactured by:
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