Lumertam®

Artemether and Lumefantrine

Composition

Lumertam® Tablet - Each tablet contains Artemether INN 20 mg and Lumefantrine INN 120 mg.

Pharmacology

Lumertam® contains a fixed ratio of 1:6 parts of Artemether and Lumefantrine respectively. Artemether is a derivative of naturally occurring substance Artemisinin. Lumefantrine is a synthetic racemic fluorine mixture belonging to the aryl amino alcohol family like other anti-malarials (e.g. Quinine, mafloquine, halofantrine). Both components act in the food vacuoles of malarial parasites, where they are thought to interfere with the conversion of haem, a toxic intermediate formed during haemoglobin breakdown, to the non-toxic haemozin (a malaria pigment). Lumefantrine is thought to interfere with the polymerization process, while Artemether generates reactive metabolites as a result of interaction between the peroxide bridge and haem iron. Both Artemether and Lumefantrine have a secondary action involving inhibition of nucleic acid - protein synthesis within the malarial parasites. **Lumertam®** did not induce resistance. **Lumertam®** is active against blood stages of *Plasmodium vivax*, but it is not active against hypnozoites. Therefore, sequential treatment with premaquine should be used to achieve hypnozoite eradication.

Indication

Lumertam® is a fixed combination of Artemether and Lumefantrine, which acts as a blood schizontocide. **Lumertam®** is indicated for: Treatment and stand by emergency treatment of adults, children and infants with acute, uncomplicated infection due to *Plasmodium falciparum* or mixed infections including *P. falciparum*. Because Artemether and Lumefantrine is effective against both drug sensitive and drug resistance *P. falciparum*. **Lumertam®** is also recommended for malaria infections acquired in areas where the parasites may be resistant to other antimalarials.*Stand by emergency treatment*: Most tourists and business travelers, considered to be non-immune, will be able to obtain prompt medical attention if malaria is suspected. However a minority at risk of infection may be unable to obtain such care within 24 hours of onset of symptoms, particularly if they are in an isolated location far from medical services. In such case, prescribers are advised to issue **Lumertam®** to be carried by the traveler for self-administration (stand by emergency treatment). Consideration should be given to official guidance regarding the appropriate use of the anti-malarial agents.

Dosage and Administration

Patients with acute malaria are frequently averse to food. The dose should be taken with high fat food or drinks such as milk. In the event of vomiting within 1 hour of administration a repeat dose should be taken. A standard 3 days treatment schedule with a total of 6 doses is recommended *Dosage in adults and children weighing 35 kg and above*: 4 tablets as a single dose at the time of initial diagnosis, again 4 tablets after eight hours, and then 4 tablets twice daily (morning and evening) on each of the following two days (Total course comprises 24 tablets).*5 to < 15 kg body weight*: 1 tablet at the time of initial diagnosis, 1 tablet again after 8 hours and then 1 tablet twice daily (morning and evening) on each of the following two days (Total course comprises of 6 tablets). *15 to < 25 kg body weight*: 2 tablets as a single dose at the time of initial diagnosis , 2 tablets again after 8 hours and then 2 tablets twice daily (morning and evening) on each of the following two days (Total course comprises 12 tablets). *25 to <35 kg body weight*: 3 tablets as a single dose at the time of initial diagnosis, 3 tablets again after 8 hours and then 3 tablets twice daily (morning and evening) on each of the following two days (Total courses comprises 18 tablets).

Contraindications

Hypersensitivity to any of the ingredients or excipients; Patients with severe malaria according to WHO definition; First trimester of pregnancy; 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 symptomatic cardiac arrythmias with clinically relevant bradycardia or with severe cardiac disease; Patients with known disturbance of electrolyte balance e.g. hypokalaemia or hypomagnesemia; Patients taking any drug which is metabolized by the cytochrome enzyme CYP2D6 (e.g. flecainide, metoprolol, imipramine, amitriptyline, clomipramine).

Side effects

It is generally very well tolerated by children and adults, with most adverse effects are of mild to moderate severity and duration. Hypersensitivity, headache, dizziness, sleep disorder, somnolence, involuntary muscle contractions, paraesthesia, hypoesthesia, abnormal gait, ataxia, palpitation, cough, abdominal pain, anorexia, diarrhoea, vomiting, nausea, pruritus, rash, arthralgia, myalgia, asthenia, fatigue.

Use in pregnancy & lactation

Contraindicated; especially in the first trimester of pregnancy. Breast feeding women should not take this preparation. Due to the long elimination half-life of Lumefantrine (4-6 days), it is recommended that breast feeding should not resume before day 28 unless potential benefits to the mother and child outweigh the risk of treatment.

Drug interaction

No such result is available.

Over dosage

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

Special warnings & precaution

This has not been evaluated for prophylaxis and is therefore not indicated. This is also not evaluated for the treatment of cerebral malaria or other severe manifestations of severe malaria including pulmonary oedema or renal failure.

Storage

Keep out of the reach of children. Store in a cool and a dry place protected from light.

How supplied

Each box of **Lumertam®** contains 6 x 4 tablets in a blister pack.

Manufactured by:

SQUARE
PHARMACEUTICALS LTD.
BANGLADESH