α-β Arteether Injection

Composition: Alpha-Beta Arteether Injection 150mg: Each 2ml contains: α-β Arteether 150mg. Arachis oil BP q.s. **Alpha-Beta Arteether Injection 225mg:** Each 3ml contains: α-β Arteether 225mg. Arachis oil BP q.s.
Excipients: Benzyl Alcohol, Tocopheryl Acetate, Arachis Oil.

Pharmacological category: Anti-malarial.

Pharmacological action: α-β Arteether is a fast acting blood schizonticidal agent for P. falciparum malaria at the erythrocytic stage. **α-β Arteether** is concentrated in parasitized erytrocytes. The functional group responsible for antimalarial activity of **α-β Arteether** is endoperoxide bridge. Iron from the digested haemoglobin of the parasite's victim reduces this bridge releasing a highly reactive free radical iron species which causes lysis of the parasitic cell. It is also proposed that **α-β Arteether** inhibits the protein synthesis and alters the ribosomal organization and endoplasmic reticulum.

Pharmacokinetics: α-β Arteether is transformed into dihydroartemisinin. It has a half life of 20 hours. It is eliminated by hepatic metabolism. The elimination is much slower compared to other artemisinin compounds.

Therapeutic indications: Severe malaria including cerebral malaria & as a second line drug in chloroquine resistant malaria cases only.

Contraindications: α-β Arteether injection is contraindicated in patients hypersensitive to artemisinin derivatives.

Dosage & directions for use: Adult: 1 Ampoule per day administered by intramuscular injection for a period of 3 days. Children: 3mg/kg per day administered by intramuscular injection for a period of 3 days. Directions for Use: The injection must be given under aseptic conditions, deep intramuscularly in the upper lateral quandrant of the buttock. No other drug should be mixed in the same syringe.

Adverse Reactions: There is no evidence of neurotoxicity in human beings with artemisinin derivatives, but neurotoxicity has been reported in experimental animals. **α-β Arteether** is usually well tolerated. However, nausea, dizziness, and depressed Gastro-intestinal tract activity can occur. Clinical, neurological, electrocardiographic and biochemical monitoring did not reveal significant toxicity. Apart from some increase in eosinophil numbers, no haematological abnormality was seen.

Warnings & precautions for use in special populations: When treating children, particular care should be taken to ensure the correct doses are given and retained. Pregnancy - Adequate studies regarding safe use of artemisinin derivatives during pregnancy are not available. Artemisinin derivatives should not be used in pregnancy as primary drugs for uncomplicated malaria cases but these can be used for treatment of severe or uncomplicated P. falciparum malaria infection in patients of multiple drug resistance, if the potential benefit justifies the potential risk to the fetus. Nursing Mothers - it is not known whether **α-β Arteether** is excreted in human milk. Because many drugs are excreted in human milk caution should be exercised while using **α-β Arteether.**

Drug interactions: Prolonged QT interval has been reported in some studies with high dosage of artemisinin derivatives. The cardiac effects of artemisinin are not very important from a clinical point of view, except that caution should be exercised against combinations with other drug that prolong the QT interval, such as quinine and halofantrine.

Symptoms of over dosage & its treatment: Overdose treatment should be symptomatic and supportive.

Storage conditions: Do not store above 30°C. Protect from sunlight. Keep out of reach of children.

Presentation: α-β Arteether Injection 150mg: Pack of 3 x 2ml.
α-β Arteether Injection 225mg: Pack of 3 x 3ml.