1.3.1 Summary of Product Characteristics (SmPC)

1. Name of the medicinal Product

a) Product Name : ALBETHER INJECTION (α-β Arteether Injection)

b) Strength

Each 2ml contains:

α-β Arteether 150.0 mg

c) Pharmaceutical Dosage form

Liquid Injection

2. Quality and Quantitative Composition

a) Qualitative declaration

α-β Arteether 150.0 mg

b) Quantitative declaration

Each 2ml contains

α-β Arteether 150.0 mg

3. Pharmaceutical form visual description of the appearance of the product

Clear, colourless to yellowish oily solution filled in 2ml amber glass ampoule.

4. Clinical Particulars

4.1 Therapeutic indications

Severe malaria including cerebral malaria and as a second line drug in chloroquine resistant malaria cases only.

4.2 Posology and method of administration:

α-β Arteether Injection is for intramuscular use only. Adult: 150 mg i.e. 1 ampoules once daily for 3 consecutive days Children - 3mg/Kg per day administered by intramuscular injection over a 3-day period The injection must be given under aseptic conditions, deep intramuscularly in the upper lateral quadrant of the buttock. No other drug should be mixed in the same syringe.

4.3 Contraindications

Arteether injection is contraindicated in patients hypersensitive to artemisinin derivatives or any of the excipients.

4.4 Special warning and precautions for use

When treating children, particular care should be taken to ensure the correct doses are given and retained.

4.5 Interaction with other medicinal products and other forms of Interactions

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

4.6 Pregnancy and lactation

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 used for treatment of severe or complicated p. Falciparum malaria infection in patients of multiple drug resistance, if the benefits justifies the potential risk to the fetus.

Nursing Mother It is not known whether α-β Arteether is secreted in human milk. Because many drugs are secreted in human milk caution should be exercised while using α-β Arteether.

4.7 Effects on ability to drive and use machine

None stated.

4.8 Undesirable effects

While neurotoxicity has been reported in experimental animals, there is no evidence of neurotoxicity in human beings with artemisinin derivatives. α-β Arteether is usually well tolerated. However, nausea, dizziness and depressed GIT 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.

4.9 Overdose

Overdose treatment should be symptomatic and supportive.

5. Pharmacological Properties:

5.1.1 Pharmacodynamic Properties

Pharmacotherapeutic group: Antimalarial ATC code: P01BE Mechanism of 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 erythrocytes. 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.

Pharmacokinetic properties

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.

5.3 Preclinical safety data

Not Applicable

6. Pharmaceutical Particulars:

6.1 List of excipients :

Ethyl Oleate BP

Benzyl alcohol BP

6.2 Incompatibilities

None known.

6.3 Shelf life

Shelf-life: 36 Months.

6.4 Special precautions for storage

Store at temperature not exceeding 30^0 C in a dry place, Protect from light.

Keep out of reach of children.

6.5 Nature and contents of container

3x2ml glass ampoule packed in a carton along with pack insert.

6.6 Special precautions for disposal <and other handling>

Not Applicable

7.0 Applicant/Manufacturer

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