1.3 Product Information

1.3.1 Summary of Product Characteristics (SmPC)

1. Name of the Medicinal Product

Alpha Beta Arteether Injection 75 mg/ml

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Composition:
Each 2ml contains:
Alpha Beta Arteether ……150 mg
Ethyl Oleate BP…….q.s
For a full list of excipients, see section 6.1

3. PHARMACEUTICAL FORM

Liquid Injection
A Clear, colourless solution filled & Sealed in glass ampoule.

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

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

4.2 Posology and method of administration

Adult: 1 Ampoule per day administered by intramuscular injection for a period of 3 days.
Children: 3 mg/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.

4.3 Contraindications

Alpha Beta Arteether Injection 75 mg/ml is contraindicated in patients hypersensitive to artemisinin derivatives.

4.4 Special warnings and special precautions for use

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 Alpha Beta Arteether is excreted in human milk. Because many drugs are excreted in human milk caution should be exercised while using Alpha Beta Arteether.

4.5 Interaction with other medicinal products and other forms of Interaction

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.

4.6 Pregnancy and lactation

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 known that whether Alpha Beta Arteether is excreted in human milk. Because many drugs are excreted in human milk caution should be exercised while using Alpha Beta Arteether.

4.7 Effects on ability to drive and use machines

Not available

4.8 Undesirable Effects

There is no evidence of neurotoxicity in human beings with artemisinin derivatives, but neurotoxicity has been reported in experimental animals Alpha Beta 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.

4.9 Overdose

Overdose treatment should be symptomatic and supportive.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: Anti-malarial

ATC code: P01BE04

Pharmacological action
Alpha Beta Arteether is a fast acting blood schizonticidal agent for P. falciparum malaria at the erythrocytic stage. Alpha Beta Arteether is concentrated in parasitized erythrocytes.
The functional group responsible for antimalarial activity of Alpha Beta Arteether is endoperoxide bridge. Iron from the digested hemoglobin 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 Alpha Beta Arteether inhibits the protein synthesis and alters the ribosomal organization and endoplasmic reticulum.

5.2 Pharmacokinetic properties

Alpha Beta 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

1. Benzyl Alcohol BP
2. Arachis Oil BP
3. Ethyl Oleate BP
4. Sodium Hydroxide BP
5. Hydrochloric Acid BP

6.2 Incompatibilities

Not Applicable

6.3 Shelf life

24 months from the date of Manufacturing.

6.4 Special precautions for storage

Store below 30^{o}C in a dry place. Store in a cool dry place.

6.5 Nature and contents of container

2 ml amber glass ampoule is used as primary packaging material for packing of the **Alpha Beta Arteether Injection 75 mg/ml**. Such 50 ampoules packed in a white corrugated box.

6.6 Instructions for use and handling

Not available

7. Manufacturer

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8. Marketing Authorization Holder

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9. Marketing Authorization Number (S)

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10. Date of First Authorization/Renewal of the Authorisation

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11. Date of Revision of the Text
