1.3.1 Summary of Product Characteristics (SmPC)

1. Name of the medicinal product

α-β Arteether Injection 150 mg/2ml

2. Qualitative and quantitative composition

Each 2ml contains:

α-β Arteether Injection 150mg

Ethyl Oleate BP q.s.

3. Pharmaceutical form

Injection

4. Clinical particulars

4.1 Therapeutic indications

α -β Arteether is indicated for the treatment of complicated and uncomplicated P. falciparum malaria, including cerebral malaria.

It is indicated as second-line treatment of Chloroquine resistant malaria.

4.2 Contraindications

α -β Arteether is contraindicated in patients showing hypersensitivity to artemisinin derivatives.

4.3 Adverse reaction

Adverse effects such as nausea, dizziness, tinnitus, depressed GI tract activity, neutropenia, ECG abnormalities including prolongation of QT interval may occur.

α-β Arteether is generally well tolerated without any significant clinical, neurological and biochemical toxicity. Neurotoxicity (at high doses, seen in animals) is manifested as gait disturbances, loss of spinal cord pain responses, incoordination, respiratory depression, convulsions and cardio respiratory arrest. Apart from some increase in eosinophil count, no other haematological abnormality has been reported.

4.4 Overdose

The pre-clinical studies of α-β Arteether have shown that LD50 value is more than 1000 mg/kg, whereas the maximum dose injected in adult is about 2.5 mg/kg per day. This confirms that the safety window for the dose administered is very wide. Hence this study concludes that α-β Arteether is well tolerated even when overdose is administered.

5. Pharmacological properties

5.1 Pharmacodynamic properties

α-β Arteether is fast acting blood schizonticidal agent for P. falciparum Malaria at the erythrocytic stage.

Arteether is concentrated in parasitized erythrocytes. The functional group responsible for antimalarial activity of α-β Arteether is "endoperoxide bridge". The researchers believe that iron from the digested haemoglobin of the parasite's victim reduces this bridge releasing a highly reactive free radical iron (IV) oxo species which rips apart the parasitic cells.

It is proposed that α-β Arteether inhibits the protein synthesis and alter the ribosomal organisation and endoplasmic reticulum.

α-β Arteether also acts on the membranes of the parasites through lipid peroxidation.

Mechanism of action

Several proposed including the production of free radicals, other reactive metabolites, and altered membrane transport properties of membranes which may inhibit nutrient flow to the parasite.

5.2 Pharmacokinetic properties

Main metabolite of α-β Arteether is Dihydroartemisinin. The half life of Dihydroartemisinin is more than 20 hours. The elimination of the drug is through hepatic metabolism and gets eliminated at a low rate as compared to other artemisinin derivatives.

6. Pharmaceutical particulars

6.1 List of excipients

Benzyl Alcohol BP

Butylated Hydroxy Toluene BP

Butylated Hydroxy Anisole BP

Propyl Gallate BP

Arachis Oil BP

6.2 Shelf life

36 months.

6.3 Special precautions for storage

Store at a temperature not exceeding 30 ^{0}C. Protect from light.

Keep medicines out of reach of children.

6.4 Nature and contents of container

A clear pale-yellow viscous solution filled in amber colour glass sealed ampoule with blue dot at constriction. This is the pack that is proposed for marketing the product.

7. Marketing authorisation holder

Alpa Laboratories Limited

33/2 A.B Road, Pigdamber, Indore (MP)

Pin Code- 453446

+91 731 4294567

+91 731 4294444

Applicant
Suitelife Pharmaceutical Limited,
Surulere, Lagos.

8. Marketing authorisation number(s)

To be allocated

9. Date of first authorisation/renewal of the authorisation

To be allocated

10. Date of revision of the text

To be allocated