SUMMARY OF PRODUCT CHARACTERISTICS (SMPC)

1. NAME OF THE MEDICINAL PRODUCT:

AFABETA

α-β ARTEETHER INJECTION 150 mg/2 ml, Solution for Injection

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 2 ml Contains:

α-β Arteether ..... 150 mg

Arachis Oil BP .....q.s.

3. PHARMACEUTICAL FORM

Solution for Injection

Clear and slightly yellow solution filled in 2 ml Amber Ampoule

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 POSOLOGY AND METHOD OF ADMINISTRATION

α -β Arteether is for INTRAMUSCULAR USE ONLY.

•The injection must be administered under aseptic conditions as deep intramuscular injection in the upper-lateral quadrant of the buttock.

•No other drug should be mixed in the same syringe.

•Adults: 150 mg once daily administrated I.M. for 3 consecutive days.

•Children: 3 mg/kg once daily administered I.M. for 3 consecutive days

4.3 CONTRAINDICATIONS

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

4.4 SPECIAL WARNINGS AND PRECAUTIONS FOR USE

During the treatment of cerebral malaria and complicated malaria, general supporting therapy should be carried out.

4.5 INTERACTION WITH OTHER MEDICINAL PRODUCTS AND OTHER FORMS OF INTERACTION

Quinine and halofantrine are known to prolong the QT interval when used along with α-β Arteether. Caution should be exercised while using these drugs.

4.6 PREGNANCY AND LACTATION

Pregnancy

Safety of α-β Arteether during pregnancy is not established. However, in case of severe infection with P. falciparum in a pregnant woman, if the potential benefit to the patient justifies the potential risk to the fetus, it may be used with caution in these women.

Lactation

It is not known whether α-β Arteether is secreted in human milk. As most of the drugs are, lactating women on α-β Arteether therapy should not breast-feed their infants.

4.7 EFFECTS ON ABILITY TO DRIVE AND USE MACHINES

Patients should be cautious when driving or operating machinery.

4.8 UNDESIRABLE EFFECTS

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, in coordination, respiratory depression, convulsions and cardio respiratory arrest.

Apart from some increase in eosinophil count, no other haematological abnormality has been reported.

4.9 OVERDOSE

There is no experience with over dosage of α-β Arteether.

5. PHARMACOLOGICAL PROPERTIES

5.1 PHARMACODYNAMIC PROPERTIES

ATC code: P01BE04

Pharmacologic class: Susquiterpine Lactones

Therapeutic class: Anti-malarial

Mechanism of action

α-β Arteether acts at the erythrocytic stage of malarial parasite. It is proposed that the intra-parasitic haem reduces the endoperoxide bridge (the functional group responsible for antimalarial activity of α-β Arteether), releasing a highly reactive free radical iron (IV) oxo species, which alkalytes and oxidises proteins and lipids causing lysis of the parasitic cell. The membrane of the parasite is damaged by lipid peroxidation and channel proteins inactivation. It is also proposed that α-β Arteether may also inactivate ribosomes and inhibit protein synthesis. Parasitic clearance times of α-β Arteether are shorter than those with chloroquine and also the response is symptomatic.

5.2 PHARMACOKINETIC PROPERTIES

- Route of administration: α-β Arteether is rapidly absorbed when administered intramuscularly.
- Metabolism: It is metabolized in the liver to the de-ethylated derivative dihydroartemisinin.
- Half-life: >20 hours.
- Elimination: Metabolized by the liver, it is eliminated slowly as compared to other artemisinin derivatives.

6. PHARMACEUTICAL PARTICULARS

6.1 LIST OF EXCIPIENTS

Benzyl Alcohol BP

Arachis Oil BP

6.2 INCOMPATIBILITIES

None stated.

6.3 SHELF LIFE

36 Months

6.4 SPECIAL PRECAUTIONS FOR STORAGE

Store below 30ºC in a dry place.

KEEP OUT OF REACH OF CHILDREN

6.5 NATURE AND CONTENTS OF CONTAINER

3 X 2 ml amber glass ampoule packed into the carton along with plastic tray and insert.

6.6 SPECIAL PRECAUTIONS FOR DISPOSAL

Not Applicable

7. APPLICANT/MANUFACTURER

MARKETED BY:

ELBE PHARMA NIGERIA LIMITED

1 African Church Close off Coker Road,Ilupeju,

Lagos, Nigeria

MANUFACTURED BY:

SWISS PARENTERALS LIMITED

Manufacturing site : 808,809 & 810 Kerala Industrial Estate,

GIDC Nr. Bavla, Dist. Ahmedabad - 382 220

Gujarat, (INDIA)

Tel: +91-7968219131

Email : export@swiss.in