1.3 Product Information

1.3.1 Summary of Product Characteristics (SmPC)

1. NAME OF THE MEDICINAL PRODUCT

Product name: ABEETA 150 INJECTION, α-β Arteether Injection 150 mg/2ml
Strength: 150 mg/2 ml
Pharmaceutical form: Liquid Injection

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 2 ml contains:
α-β Arteether 150 mg
Ethyl Oleate BP q.s.

For complete list of excipients please see Section 6.1

3. PHARMACEUTICAL FORM

A Clear pale yellow liquid.

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

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

4.4 SPECIAL WARNING AND PRECAUTION 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 INTERACTION

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 FERTILITY, 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 THE ABILITY TO DRIVE AND USE MACHINES
Not Known.

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 PARTICULARS
5.1 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.

5.2 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 PRE-CLINICAL SAFETY
Preclinical studies of arteether injection have been completed. No intolerance has yet been observed.

6. PHARMACEUTICAL PARTICULARS
6.1 LIST OF EXCIPIENTS
Butylated Hydroxyanisole BP
Butylated Hydroxytoluene BP
Propyl Gallete BP
Ethyl Oleate BP

6.2 INCOMPATIBILITIES
None

6.3 SHELF LIFE
24 months

6.4 SPECIAL PRECAUTIONS FOR STORAGE
Store below 30°C. Protect from light & moisture

6.5 NATURE AND CONTENTS OF CONTAINER
α-β Arteether Injection 150 mg/2 ml is filled in 2 ml amber glass ampoule. 3 filled ampoule is labeled and packed in carton along with package insert.

6.6 SPECIAL PRECAUTIONS FOR DISPOSAL AND OTHER HANDLING
Not applicable.

7. MARKETING AUTHORIZATION HOLDER
SAKAR HEALTHCARE LIMITED
Block No. 10-13, Sarkhej-Bavla Highway,
Changodar, Ahmedabad - 382213, Gujarat, India

8. MARKETING AUTHORIZATION NUMBER
Will be included after marketing authorization

9. DATE OF FIRST AUTHORIZATION /RENEWAL OF THE AUTHORIZATION
Will be included after marketing authorization

10. DATE OF REVISION OF TEXT
Will be included after marketing authorization