

### 1.3 PRODUCT INFORMATION

#### 1.3.1 SUMMARY OF PRODUCT CHARACTERISTICS

##### 1. Name of the Medicinal Product

###### 1.1 Product Name :

**Brand Name** : IBAJECT

**Generic Name** :  $\alpha$  -  $\beta$  ARTEETHER INJECTION

**1.2 Strength** : 75mg/ml

##### 2. Qualitative and Quantitative Composition:

**Each ml contains:**

$\alpha$  -  $\beta$  Arteether.....75 mg

Arachis oil BP.....Q.S

##### 3. Pharmaceutical Form:

Solution for Injection

##### 4. Clinical Particular

###### 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

$\alpha$ - $\beta$  Arteether Injection is for intramuscular use only.

Adult: 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 Contraindication

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

###### 4.4 Special warnings 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 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 be used for treatment of severe or complicated *P. falciparum* malaria infection in patients of multiple drug resistance, if the benefits justify the potential risk to the fetus.

**Nursing Mother**

It is not known whether  $\alpha$ - $\beta$  Arteether is secreted in human milk. Because many drugs are secreted in human milk caution should be exercised while using  $\alpha$ - $\beta$  Arteether.

**4.7 Effects on 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.  $\alpha$ - $\beta$  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 Pharmacodynamic Properties**

Pharmacotherapeutic group: Antimalarial

ATC code: P01BE02

Mechanism of 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 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  $\alpha$ - $\beta$  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.

**6. Pharmaceutical Particulars****6.1 List of Excipients**

Benzyl Alcohol

all-rac – Alpha – Tocopheryl Acetate

Arachis oil

**6.2 Incompatibilities**

None known

**6.3 Shelf life**

36 Months

**6.4 Special precautions for storage**

Store between 2°C to 8°C.

**6.5 Nature and contents of container**

2 ml Amber Glass Ampoule

**7. Marketing authorization holder**

Name : **M/S Hanbet Pharmaceuticals Ltd.**

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Nigeria