

**Summary of Product Characteristics (SPC)**

**1. Name of the medicinal product**

Alpha Beta Arteether Injection 150mg/2ml

**1.1 International Non-Proprietary Name (INN)**

Alpha Beta Arteether Injection 150mg/2ml

**1.2 Strength**

150mg/2ml

**1.3 Pharmaceutical form**

Liquid Injection

**2. Qualitative and quantitative composition**

Each 2ml contains:

Alpha Beta Arteether 150mg

Arachis Oil q.s.

**3. Pharmaceutical form**

Liquid Injection

**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**

ARH is for intramuscular use only.

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**

$\alpha$ - $\beta$  Arteether injection is contraindicated in patients hypersensitive to artemisinin derivatives

**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.

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#### **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 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 potential benefit justifies the potential risk to the fetus.

**Lactation:** It is not known whether  $\alpha$ - $\beta$  Arteether is secreted in human milk. Caution should be exercised when  $\alpha$ - $\beta$  Arteether injection used in lactating mother

#### **4.7 Effects on ability to drive and use machines**

There have been no studies to investigate the effect of  $\alpha$ - $\beta$  Arteether on driving performance or the ability to operate machinery.

#### **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 of overdose should consist of general supportive measures.

### **5. Pharmacological properties**

#### **5.1 Pharmacodynamic properties**

$\alpha$ - $\beta$  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

Pharmacokinetics of Artesunate

|                                |          |
|--------------------------------|----------|
| <b>Absorption</b>              |          |
| Oral bioavailability           | ---      |
| Food effect                    | ---      |
| <b>Distribution</b>            |          |
| Volume of distribution (mean)  | -----    |
| Plasma protein binding         | ---      |
| Tissue distribution            | ---      |
| <b>Metabolism</b>              |          |
|                                | --       |
| Active metabolite(s)           | --       |
| <b>Elimination</b>             |          |
| Elimination half life          | 20 hours |
| Mean systemic clearance (Cl/F) | ---      |
| % of dose excreted in urine    | ---      |
| % of dose excreted in faeces   | ---      |

## 5.3 Preclinical safety data

Not Applicable

## 6. Pharmaceutical particulars

### 6.1 List of excipients

| S.No. | Name of excipients |
|-------|--------------------|
| 1.    | Ethyl Oleate IP    |
| 2.    | Benzyl alcohol BP  |
| 3.    | Arachis Oil BP     |

### 6.2 Incompatibilities

None Known.

### 6.3 Shelf life

36 Months



## **SCOTT-EDIL PHARMACIA LTD.**

**Plot No.56, EPIP, Phase-I Jharmajri, Baddi, Distt. Solan  
(H.P.), 173205 INDIA**

### **6.4 Special precautions for storage**

Store at a temperature not exceeding 30°C in a dry place. Protect from light.

### **6.5 Nature and contents of container**

03 Amber colour ampoules of 2ml in a tray pack in a unit carton along with a leaflet.

### **6.6 Special precautions for disposal and other handling**

None Known.

### **7. Manufactured By**

**Scott-Edil Pharmacia Limited,**  
56, EPIP, Phase-I, Jharmajri,  
Baddi, Distt. Solan- 173205 (H.P)  
INDIA

### **8. Marketed By**

**Scott-Edil Pharmacia Limited,**  
56, EPIP, Phase-I, Jharmajri,  
Baddi, Distt. Solan- 173205 (H.P)  
INDIA

### **9. Date of revision of the text**

JUNE 2022

### **10. DOSIMETRY (IF APPLICABLE)**

Not applicable

### **11. INSTRUCTIONS FOR PREPARATION OF RADIOPHARMACEUTICALS (IF APPLICABLE)**

Not Applicable

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