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| **1.3** | **Product Information** |

## 1.3.1 PRESCRIBING INFORMATION

## SUMMARY OF PRODUCT CHARACTERISTICS

### 1.NAME OF THE MEDICINAL PRODUCT

ARTELIFE (α-ß ARTEETHER INJECTION 150 mg/2ml)

### 2. QUALITATIVE AND QUANTITATIVE COMPOSITION

**Composition:**

Each 2ml contains:

α-β Arteether (In House) 150 mg

Arachis Oil q.s

### 3. PHARMACEUTICAL FORM

Liquid 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. Severe malaria including cerebral malaria and as a second line drug in chloroquine resistant malaria cases only. α- β arteether is a fast acting blood schizonticidal agent for P. falciparum malaria at the erythrocytic stage.

#### 4.2 Dosage and administration:

Posology

α / β arteether is for intramuscular use only.

**Adult** - 150mg i.e. 1 ampoule of b arteether once daily for 3 consecutive days.

**Children** - 3mg/Kg per day administered by intramuscular injection over a 3-day period.

Method of administration

Intramuscular Injection

#### 4.3 Contraindications:

Arteether is contraindicated in pregnant females below 16 years, patients with hypersensitivity to Arteemether or other Artemisinin compounds. Arteether is not recommended in the first trimester of pregnancy because of limited data.

#### 4.4 Special Warnings and Precautions for Use

Not applicable.

### 4.5 Interaction with other Medicinal products and other forms of Interaction

Arteether should not be used with drugs that strongly inhibit the cytochrome P450 enzyme CYP3A4 like HIV protease inhibitors or ketoconazole or those that strongly induce the CYP3A4 enzyme like carbamazepine and phenobarbital.

• Arteether interacts severely with quetiapine and moderately with mefloquine

### 4.6 Fertility, pregnancy and lactation

It should be used with caution in the first trimester of pregnancy since some fetus absorption has been observed.

### 4.7 Effects on Ability to Drive and Use Machines:

No studies on the effects on the ability to drive and use machines have been performed

### 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 / 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.

### 4.9 Overdose

Although no case of overdosage has been documented, in case of accident, symptomatic treatment is recommended under the instruction of doctors

## 5. PHARMACOLOGICAL PROPERTIES

### 5.1 Pharmacodynamic Properties

Pharmacotherapeutic group: antimalarials, ATC code: P01BE02.

### 5.2 Pharmacokinetic properties:

The drug is absorbed rapidly and completely after IM injection. The maximum blood concentration of the drug is observed in about 7 hours after I.M. injection of 10mg/kg in human body. The peak value is about 0.8g/ml with the plasma half-life of about 13 hours. It is widely distributed in the body with the highest level found in the brain and followed by liver and kidney. It is mainly excreted in the feces with a part in urine.

### 5.3 Preclinical safety data

There is no preclinical data available that is of relevance to the prescriber

## 6. PHARMACEUTICAL PARTICULARS

### 6.1 LIST OF EXCIPIENTS:

Benzyl alcohol BP , Butylated hydroxyl Anisole BP and Arachis oil BP are used as excipients in the manufacturing process of α-β Arteeether Injection 75 mg/ml.

**6.2 Shelf Life**

36 Months

**6.3 Special Precautions for Storage**

Protect from light.

**6.4 Nature and Contents of Container**

2 ML AMBER USP TYPE I AMPOULE

**6.5 Special Precautions for Disposal and Other Handling**

No special requirements

**7. MARKETING AUTHORISATION HOLDER**

**Ciron Drugs & Pharmaceuticals Pvt. Ltd.**
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**8. MARKETING AUTHORISATION NUMBER(S)**

None

**9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION**

Not applicable