## 1. NAME OF THE MEDICINAL PRODUCT

**EMBAETHER** (α – β Arteether Injection)

## 2. QUALITATIVE AND QUANTITATIVE COMPOSITION

**Each 2ml contains:**

| | | |
|---|---|---|
| α – β Arteether | | 150 mg |
| Benzyl Alcohol | BP | 2% v/v |
| (as preservative) | | |
| Arachis oil | BP | q.s. |

## 3. PHARMACEUTICAL FORM

Solution for Injection

## 4. CLINICAL PARTICULARS

### 4.1 Therapeutic Indications

Alpha-Beta Arteether injection is used for the treatment of severe falciparum malaria active against P. falciparum strains that are resistant to chloroquine, mefloquine, halofantrine, quinine, pyrimethamine, cycloguanil and amodiaquine. Alpha-Beta Arteether injection is also used for the treatment of uncomplicated falciparum malaria.

### 4.2 Posology and Method of Administration

**Alpha/beta Arteether in Adults:**

Intramuscular injection of one ampoule, containing 150mg / arteether, daily for 3 consecutive days (i.e. total dose 480 mg irrespective of body weight or 3mg/kg/day for a 50 kg adult).

**Child dose:**

Intramuscular injection of 3mg / arteether/kg body weight daily for 3 consecutive days.

**Children and adolescents up to the age of 16 years only:**

Intramuscular injection of 4.8mg/kg body weight as a loading dose followed by 1.6mg/kg body weight administered 6, 24, 48 and 72 hours after the loading dose.

The injection can alternatively be continued on further consecutive days until the patient can take oral therapy with another effective Antimalarial drug.

**Method of Administration**

For Intramuscular Use Only.

### 4.3 Contraindications

Alpha-Beta Arteether injection is contraindicated in patients hypersensitive to artemisinin derivatives. Patients who are taking any drug which is metabolised by the cytochrome enzyme CYP2D6 (e.g. metoprolol, imipramine, amitryptyline, clomipramine).

Patients with a family history of sudden death or of congenital prolongation of the QTc interval on electrocardiograms, or with any other clinical condition known to prolong the QTc interval.

Patients taking drugs that are known to prolong the QTc interval (proarrythmic).

**These drugs include:** Antiarrhythmics of classes IA and III, neuroleptics, antidepressive agents, certain antibiotics including some agents of the following classes: macrolides, fluoroquinolones, imidazole and triazole antifungal agents, certain non-sedating antihistamines (terfenadine, astemizole), cisapride & flecainide.

## 4.4 Special Warning and Precautions for Use

Use of Alpha-Beta Arteether injection is restricted to children and adolescents under the age of 16 because of the possibility that it may have an effect on the heart.

Product must be used only via the intramuscular route. The loading dose should be equally divided and injected anteriorly into both thighs with each subsequent dose injected into alternating thighs.

The use of Alpha-Beta Arteether injection for the treatment of severe malaria in patients with pre-existing renal or liver failure has not been studied.

Use caution when using arteether in the case of medicine induced fever, patients with heart disease and drug resistance.

## 4.5 Interaction with Other Medicinal Products and Other Forms of Interaction

All drugs interact differently for person to person.

**Interaction with Medicine**

Quetiapine severe

Mefloquine moderate

**Disease interactions**

**Liver Disease severe**

This medicine should be administered with caution in patients having an impaired liver function. Appropriate diagnostic tests must be performed before determining the dose regimen. Suitable dose adjustment and frequent monitoring may be needed to ensure safe and effective use.

**Kidney Disease moderate**

This medicine should be administered with caution in patients having an impaired kidney function. Suitable dose adjustment and frequent monitoring may be needed to ensure safe and effective use.

## 4.6 Pregnancy and Lactation

Use of this medicine in pregnant women is not recommended unless absolutely necessary. The effect of this medicine on pregnancy is not clearly established and hence should be used only in life-threatening situations.

Use of this medicine while breastfeeding is not recommended unless necessary. Your doctor will determine whether or not to use this medicine.

## 4.7 Effects on Ability to Drive and Use Machines

Do not drive or operate machinery.

Do not stop medication.

Monitor blood test once a week

## 4.8 Undesirable Effecsts

**Immune system disorders**

Hypersensitivity

**Metabolism and nutrition disorders**

Decreased appetite, Psychiatric disorders, Sleep disorders, Insomnia

**Nervous system disorders**

Headache, Dizziness, Paraesthesia, Ataxia, hypoaesthesia, clonus

**Cardiac disorders**

Palpitations, Electrocardiogram QT prolonged

**Respiratory, thoracic and meditational disorders**

Cough, Gastrointestinal disorders, Vomiting, Abdominal pain, Nausea, Diarrhea

**Hepatobiliary disorders**

Liver function tests increased

**Skin and subcutaneous tissue disorders**

Rash, Pruritus, Urticaria, Angioedema

**Musculoskeletal and connective tissue disorders**

Arthralgia, Myalgia

**General disorders and administration site conditions**

Asthenia, Fatigue, Gait disturbance

## 4.9 Overdose

Do not use more than prescribed dose. Taking more medication will not improve your symptoms; rather they may cause poisoning or serious side-effects.

In cases of suspected over-dosage symptomatic and supportive therapy should be given as appropriate, which should include ECG and blood potassium monitoring.

## 5.0 PHARMACOLOGICAL PROPERTIES

### 5.1 Pharmacodynamic Properties

**ATC Code:** P01BE02

**Pharmacotheraputic Group:** Antimalarial

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 which inhibits the protein synthesis and alters the ribosomal organization and endoplasmic reticulum.

### 5.2 Pharmacokinetic properties

Alpha-Beta Arteether is absorbed well after intra muscular or oral administration. The drug is fully metabolized and the major metabolite is dihydroartemisinin, which also has anti parasite effects. It is rapidly cleared, predominantly through the bile.

### 5.3 Preclinical Safety Data

There are no preclinical data of relevance to the prescriber which are additional to that already included in other sections of the SmPC.

## 6.0 PHARMACEUTICAL PARTICULARS

### 6.1 List of Excipients

- Benzyl Alcohol BP
- Arachis Oil BP

### 6.2 Incompatibilities

Not applicable

### 6.3 Shelf Life

36 Months

### 6.4 Special Precautions for Storage

Do not Store above 30°C. Protect from light.

**Keep all medicines out of the reach of children.**

### 6.5 Nature and Contents of Container

3 × 2ml amber coloured glass ampoules packed in a unit carton along with pack insert.

### 6.6 Special Precautions for Disposal and Other Handling

No special requirements.

## 7.0 APPLICANT/SOLE AGENT

**EMBASSY PHARMACEUTICAL & CHEMICAL LTD.**

41, Ademola Street, South West Ikoyi,

Lagos, Nigeria. Tel.: 01-2900791

**Manufacturer**

**LABORATE PHARMACEUTICALS INDIA LIMITED**

31, Rajban Road, Paonta Sahib, Distt. Sirmour,

Himachal Pradesh - 173025, India

With Braille
77x15x58mm

Brand Name Embossed
Back Printing Embassy

# EMBAETHER®



## EMBAETHER®

α-β Arteether Injection 150 mg/2 ml

**3 x 2ml** FOR INTRAMUSCULAR USE ONLY




# EMBAETHER®




**Composition:**
**Each 2 ml contains:**

| | |
|---|---|
| α-β Arteether | 150 mg |
| Benzyl Alcohol (As Preservative) | BP 2% v/v |
| Arachis Oil BP | q.s. |

DOSAGE: As directed by the Physician.

STORAGE: Do not store above 30°C, protect from light

KEEP ALL MEDICINES OUT OF THE REACH OF CHILDREN.

Read the pack insert carefully

Mfg. Lic. No.: S-MB/10/66

Batch No.:

Mfg. Date:

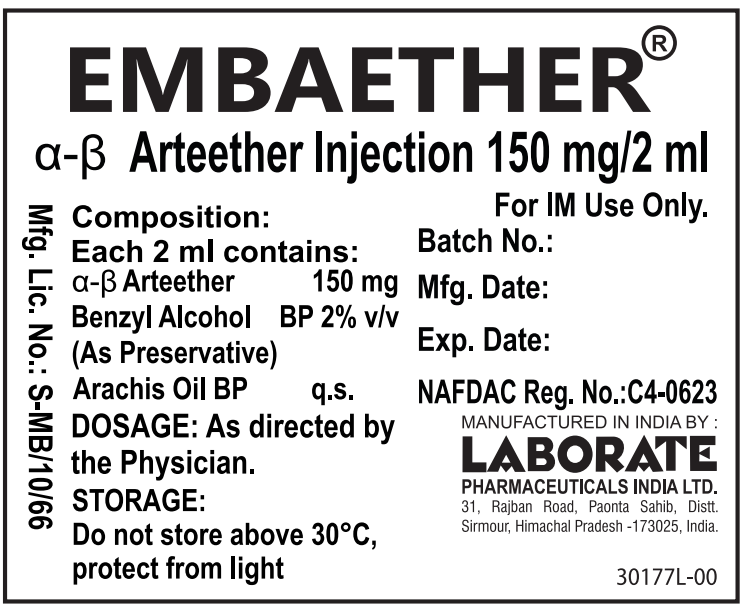
Exp. Date:

NAFDAC Reg. No.:C4-0623

MANUFACTURED IN INDIA BY :
LABORATE PHARMACEUTICALS INDIA LTD.
31, Raban Road, Paonta Sahib, Distt. Sirmour, Himachal Pradesh -173025, India.

*Quality Product of:*
EMBASSY
PHARMACEUTICAL & CHEMICALS LTD.
Lagos Nigeria

# 31x25mm
# Transparent Sticker
# White Colour Screen Printing



70x135 mm

*"For Medical/Pharmacy Professionals only"*

# EMBAETHER

## α-β Arteether Injection

**FOR I.M. USE ONLY**

**DOSAGE FORM AND STRENGTH**
**Injection:** Liquid Injection
**Strength:**
α-β Arteether 150mg/2ml
**HISTORY OF ACTIVE INGREDIENTS**
α-β Arteether is an ethyl ether derivative of artemisinin which is an efficient schizontocidal drug in mild Falciparam malaria.
**NET CONTENT**
Each 2ml contains:
α-β Arteether 150mg
Benzyl Alcohol B.P. 2.0%v/v
(As Preservative)
Arachis Oil B.P. q.s.
**CLINICAL PHARMACOLOGY:**
**ATC CODE: P01BE**
**PHARMACODYNAMICS**
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 erytrocytes. The functional group responsible for antimalarial activity of α-β arteether is endoperoxide bridge which inhibits the protein synthesis and alters the ribosomal organization and endoplasmic reticulum.
**PHARMACOKINETICS**
α-β arteether are absorbed well after intra muscular administration. The drug is fully metabolised and the major metabolite is dihydroartemisinin, which also has anti parasite effects. It is rapidly cleared, predominantly through the bile.
**INDICATION & USAGE**
α-β arteether is a fast acting blood schizonticide specifically indicated for the treatment of chloroquine-resistant Plasmodium falciparum malaria and cerebral malaria cases. It is a semi-synthetic derivative of artemisinin, a natural product of the Chinese plant Artemisia annua. It is currently only used as a second line drug in severe cases of malaria.
**CONTRAINDICATIONS**
α-β arteether injection is contraindicated in patients hypersensitive to artemisinin derivatives. Arteether Injection should not be taken if you have the following conditions:
-ECG abnormalities
-Lactation
-Pregnancy
**INTERACTIONS**
Interacts with other drugs like amiodarone, astemizole, bretylium, disopyramide, erythromycin, halofantrine, mefloquine, probucol, procainamide, quinidine, quinine, sotalol, terfenadine.
**WARNINGS**
α-β arteether must not be used in the first trimester of pregnancy in situations where other suitable and effective antimalarials are available.
**PREGNANCY**
Contraindicated.
**LACTATION**
Contraindicated.
**Keep all medicines out of the reach of children.**
**PRECAUTIONS**
Do not drive or operate machinery.
Do not stop medication.
Monitor blood test once a week.
**ADVERSE EFFECTS**
Nausea, cough and dizziness. Body ache, general weakness, vomiting, pain at injection site, abdominal pain, leg pain, chills and rigors and watery diarrhoea.
**DRUG ABUSE & DEPENDENCE**
Not applicable.
**SYMPTOMS OF OVERDOSE & ANTIDOTE**
In cases of suspected overdosage symptomatic and supportive therapy should be given as appropriate, which should include ECG.
**DOSAGE & ADMINISTRATION**
**Adults-** 150mg/day for three days.
**Children:** 3 mg/kg per day administered by intramuscular injection over a period of 3 days.
Or as directed by the Physician.

The injection must be given in aseptic conditions, deep intramuscularly in the upper external quadrant of the buttock. No other drug should be mixed in the same syringe.

**THE PREPARATION FOR USE**
Not Applicable
**PRESENTATION**
3x2ml Ampoule packed in a unit carton along with patient information leaflet.
**STORAGE CONDITIONS**
Do not store above 30°C, protect from light
**Any Other Information**
The drug should not be promoted or used as a first line treatment for malaria.

30177I-00

MANUFACTURED IN INDIA BY :
LABORATE PHARMACEUTICALS INDIA LTD.
31, Rajban Road, Paonta Sahib, Distt. Sirmour, Himachal Pradesh -173025, India.

NAFDAC Reg. No.:C4-0623
Quality Product of:
EMBASSY PHARMACEUTICAL & CHEMICALS LTD.
Lagos Nigeria