1. NAME OF THE MEDICINAL PRODUCT

Brand Name: --
Generic Name: ALPHA BETA ARTEETHER INJECTION 150MG/2ML

Composition:
Each 2ml contains:
Alpha Beta Arteether (In House) …….. 150 mg
Ethyl Oleate BP ……..q.s

Pharmaceutical form: Liquid Injection

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Sr. No	Material	Specification	Rationale	Composition	Overage %	Qty /ml	Qty/Batch Size 135 lit
1.	α β Arteether	IH	Active ingredients	150 mg/ 2 ml	---	75 mg	10.125 kg
2.	Ethyl Oleate	BP	Vehicle	QS	---	Qs to 1 ml	135 lit

Where,
BP = British Pharmacopoeia
IH = In House Specification

3. PHARMACEUTICAL FORM

Liquid Injection

4. Clinical particulars

4.1 Therapeutic indications

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

4.2 Posology and method of administration

Posology

Adult: 150 mg. Once daily for 3 consecutive days
Children: 3 mg/kg per daily administered by intramuscular injection over a period of 3 days.

4.3 Contraindications

Arteether is Çontraindicated in patients showing hypersensitivity to artemisinin derivative and during Pregnancy Special warnings and precautions for use

4.4Interaction with other medicinal products and other forms of interaction

Quinine and Halofantrine are known to prolong the QT interval when used along with Arteether.Caution should be exercised when using these drugs

4.5 Pregnancy and Lactation

Safety of arteether during pregnancy is not established. However, in case of severe infection with P. falciparam in pregnant woman, if the potential benefits to the patients justifies the potential risk to the fetus, it may be used with caution in these women.

It is not known whether Arteether is secreted in human milk. As most of the drugs are, lactating women on Arteether therapy should not breast-feed their infants

4.6 Effects on ability to drive and use machines

Patients receiving alpha beta arteether should be warned that dizziness or fatigue/asthenia may occur in which case they should not drive or use machines.

4.7 Undesirable effects

Headache, nausea cough and dizziness. Body ache, general weakness, vomiting, pain at inj site, abdominal pain, leg pain, chills and rigors and watery diarrhea.

4.8 Overdose

Altrough no case of overdose has been documented, in case of accidental overdose, symptomatic treatment is recommended under the instruction of Doctor.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamics properties Pharmacotherapeutic group: Antimalarial,

ATC code: P01BE04

Mechanism of action:
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.
Arteether acts at the erythrocytic stage of malarial parasite. It is proposed that the intra-parasite haem reduces the bridge (the functional group responsible for antimalarial activity of Arteether), releasing a highly reactive free radical iron (IV) oxo species, which alkalytes and oxidizes proteins and lipids causing lysis of the parasitic cell. The membrane of the parasite is damaged by lipid peroxidation and channel protein inactivation. It is also proposed that arteether may also inactivate ribosomes and inhibit protein synthesis. Parasitic clearance times of arteether are shorter than those with chloroquine and also the response is symptomatic

5.2 Pharmacokinetic properties

Arteether is the ethyl ether derivative of artemisinin. Its quick onset of effect and high efficacy in bringing down the parasite load are the properties which make this drug a suitable therapeutic option against falciparum infection.
Metabolism: Rapidly hydrolysed to the active metabolite dihydroartemisinin. Excretion: Elimination half-life: about 4-11 hr after IM or oral admin.

5.3 Preclinical safety data

Not Available.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Ethyl Oleate.

6.2 Incompatibilities

Nil.

6.3 Shelf life

36 months

6.4 Special precautions for storage

Store at temperature below 25^0C in a dry place. Protect from light.

6.5 Nature and contents of container <and special equipment for use, administration orimplantation>

(3×2ml) amber glass ampoules packed in PVC tray along with Carton and pack insert

6.6 Special precautions for disposal <and other handling>

No special requirements

7. <APPLICANT >

Malven Medics Int'l Co.Ltd.

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