

Module I Administrative Information**Product Name: ALPHA BETA ARTEETHER INJECTION 150MG/ 2ML**

Summary Product Characteristics**1. Name of the proprietary product: --- SUDARA INJECTION****Name of the nonproprietary International Product: ALPHA BETA ARTEETHER INJECTION 150MG/ 2ML****Route of Administration:** Intramuscular injections**2. Qualitative and Quantitative composition:**

Sr. No	Material	Specification	Rationale	Composition	Overage %	Qty /ml	Qty/Batch Size 570 lit
1.	$\alpha \beta$ Arteether	IH	Active ingredients	150 mg/ 2 ml	---	75 mg	42.750 kg
2.	Arachis Oil	BP	Vehicle	QS	---	Qs to 1 ml	570 lit

Where,

BP = British Pharmacopoeia

IH = In House Specification

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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:

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 Contraindicated in patients showing hypersensitivity to artemisinin derivative and during Pregnancy.

4.4 Special warnings and precautions for use

During the treatment of cerebral malaria and complicated malaria, general supporting therapy should be carried out.

4.5 Interaction 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.

4.6 Pregnancy and Lactation:

Safety of arteether during pregnancy is not established. However, in case of severe infection with *P. falciparum* 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.

4.7 Effects on the 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.

4.8 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.

4.9 Overdose

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

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5. Pharmacological Particulars:

5.1 Pharmacodynamic 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 alkylates 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 Pre-clinical Safety:

Not Available.

6. Pharmaceutical Particulars:

List of Excipients:

Arachis Oil .

6.2 Incompatibilities:

Nil.

6.3 Shelf Life: 36 months

6.4 Special Precautions for storage:

Store at temperature below 25°C in a cool and dry place.

6.5 Nature and contents of container:

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

6.6 Special precautions for disposal and other handling:

No special requirements.

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Product Name: ALPHA BETA ARTEETHER INJECTION 150MG/ 2ML

7. Marketing Authorization Holder:

MARKETED BY :

TIM GREAT PHARMA VENTURES LIMITED

NO. 39, NIGER STREET, OFF M/M WAY, OPPOSITE GLO OFFICE, KANO, KANO STATE, NIGERIA.

MANUFACTURED BY: PHARMAX INDIA PVT LTD.,

9, Kurla Industrial Estate, Ghatkopar west, Mumbai-400086

8. Marketing Authorization Number: ---

9. Date of first Authorization /renewal of the authorization: ---

10. Date of revision of text: