



Bharat Parenterals Limited

Registered Office & Works:
Vil. Haripura, Ta. Savli, Dist. Vadodara - 391520 (Guj.) India.
Tele Fax : (02667)-251679, 251680, 251669, 99099 28332.
E-mail: bplbrd@bplindia.in, info@bplindia.in, Web.: www.bplindia.in
CIN NO: U24231GJ1992PLC018237

BIOMETHER - SUMMARY OF PRODUCT CHARACTERISTICS (SmPC)

Summary of Product Characteristics (SmPC)

1. Name of the medicinal product:

Generic Name/INN Name: α - β Arteether Injection

Trade Name: BIOMETHER

Strength:

Each 2 ml contains:

α - β Arteether 150 mg.
Arachis Oil BP q. s.

2. Qualitative and Quantitative composition:

Sr.No.	Ingredients.	Spec.	Std. Qty (mg/ml)	Function
1.	α - β Arteether	IH	75	Active
2.	Benzyl alcohol	BP	75	Preservative
3.	Arachis Oil	BP	q.s	Vehicle

3. Pharmaceutical form:

Dosage Form: Liquid injection

Visual & Physical characteristics of the product: A slightly yellow colour liquid filled & sealed in an amber colour glass ampoule.

4. Clinical particulars

4.1. Therapeutic indications:

Arteether is indicated for the treatment of severe malaria including cerebral malaria and as a second line drug in chloroquine resistant malaria cases only.

4.2. Posology and method of administration:

α / β Arteether is for intramuscular use only.

Adult - 150mg i.e. 1 ampoule of α / β Arteether once daily for 3 consecutive days.
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:

α / β Arteether injection is contraindicated in patients hypersensitive to artemisinin.





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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. 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 uncomplicated *P. falciparum* malaria infection in patients of multiple drug resistance, if the potential benefit justifies the potential risk to the fetus. Nursing mothers- it is not known whether α - β Arteether is excreted in human milk. Because many drugs are excreted in human milk caution should be exercised while using α - β Arteether.

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.

Nursing mothers - It is not known whether Arteether is excreted in human milk. Because many drugs are excreted in human milk caution should be exercised while using Arteether.

4.7. Effects on ability to drive and use machines:

Not performed

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 diarrhoea.

4.9 Overdose

Overdose treatment should be symptomatic and supportive.





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5. Pharmacological properties:

5.1. Pharmacodynamic properties:

Pharmacotherapeutic group: Antimalarial

ATC code: P01BE04

Mechanism of action

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 erythrocytes. The functional group responsible for antimalarial activity of α - β 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 α - β Arteether inhibits the protein synthesis and alters the ribosomal organization and endoplasmic reticulum.

5.2. Pharmacokinetic properties:

α - β Arteether is transformed into dihydroartemisinin. It has a half-life of 20 hours. It is eliminated by hepatic metabolism. The elimination is much slower compared to other artemisinin compounds.

5.3 Preclinical safety data

Not available

6. Pharmaceutical particulars:

6.1. List of Excipients:

Benzyl alcohol BP

Arachis oil BP

6.2. Incompatibilities:

Not applicable.

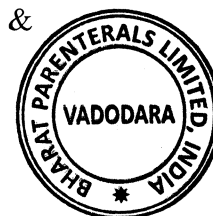
6.3. Shelf life: 24 months

6.4. Special precautions for storage:

Store in a cool, dry place at a temperature not exceeding 25°C, Protect from light & humidity. Do not freeze.

6.5. Nature and contents of container:

3 x 2 ml ampoule





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6.6. Special precautions for disposal:

No special requirements.

Any unused product or waste material should be disposed of in accordance with local requirements.

7. Applicant:

Biomedicine Sckivs Pharm.Nig Ltd,

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Name and Address of manufacturer:

M/s. Bharat Parenterals Limited

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