1.3 Product Information

1.3.1 Summary Product Characteristics (SPC):

Enclosed

1.3.1 Summary Product Characteristics

1. Name of the proprietary product:

Name of the nonproprietary International Product: α-β Arteether Injection 150 mg/2 mL

Route of Administration: Intramuscular

2. Qualitative and Quantitative composition:

BATCH SIZE: 23810 Ampoules

Sr. No.	Ingredient	Grade	Each ml contain	Overages	Qty /Batchs	Function
1.	α – β Arteether	IHS	75 mg	5%	3.94 kg*	Antimalarial
2.	Benzyl Alcohol	BP	20 mg	-	1 kg	Preservatives
3.	Ethyl Oleate	BP	250 mg	-	12.5 kg	Lubricant & plasticizer
4.	Arachis oil	BP	q.s. to 1 mL	-	q.s. to 50 L	Vehicle

*Considering 100% assay.

3. Pharmaceutical Form: Injection

4. 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.

Dosage & administration:
Arteether is for INTRAMUSCULAR USE ONLY.

- The injection must be administered under aseptic conditions as deep intramuscular injection in the upper-lateral quadrant of the buttock.
- No other drug should be mixed in the same syringe.

Adults:
150 mg once daily administrated I.M. for 3 consecutive days.

Children:
3 mg/kg once daily administered I.M. for 3 consecutive days.

Contraindications:
Arteether is contraindicated in patients showing hypersensitivity to artemisinin derivatives.

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

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

Side Effects:
Adverse effects such as nausea, dizziness, tinnitus, depressed GI tract activity, neutropenia, ECG abnormalities including prolongation of QT interval may occur.
Arteether is generally well tolerated without any significant clinical, neurological and biochemical toxicity. Neurotoxicity (at high doses, seen in animals) is manifested as gait disturbances, loss of spinal cord pain responses, in coordination, respiratory depression, convulsions and cardio respiratory arrest.
Apart from some increase in eosinophil count, no other haematological abnormality has been reported.

Pregnancy & Lactation:
Safety of Arteether during pregnancy is not established. However, in case of severe infection with P. falciparum in a pregnant woman, if the potential benefit to the patient 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.

5. Pharmacological classification & ATC Classification:
P01BE04: Antimalarial

Pharmacology:
Arteether acts at the erythrocytic stage of malarial parasite. It is proposed that the intra-parasitic haem reduces the endoperoxide bridge (the functional group responsible for antimalarial activityof Arteether), releasing a highly reactive free radical iron(IV) oxo species, which alkalytes and oxidises proteins and lipids causing lysis of the parasitic cell. The membrane of the parasite is damaged by lipid peroxidation and channel proteins' 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

6. Pharmaceutical Particulars:

List of Excipients:

Arachis oil BP
Benzyl Alcohol BP
Ethyl Oleate BP

Incompatibilities: Not applicable.

Shelf Life: 24 months.

Special Precautions for storage:
Store at a temperature not exceeding 30°C. Protect from light.

Nature and contents of container:
3 Ampoules of 2 ml kept in A Paper tray and packed in printed carton along with products insert.

Special precautions for disposal and other handling:
No special requirements.

7. Marketing Authorization Holder:

NAZA ASSOCIATES NIGERIA LIMITED
NO 1 OHAMU STREET OLOJOJO OWOROSHOKI
LAGOS STATE NIGERIA

8. Marketing Authorization Number: ---
A4-8881

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

10. Date of revision of text: