1.3 Product Information

1.3.1 Summary of product characterization

1. Name of the Medicinal Product

(a) Product Name : Fexomal 225 Injection

(b) Strength : 225mg/3mL

(c) Pharmaceutical Dosage Form: Injection

2. Quality and Quantitative Composition

(a) Qualitative Declaration, the active substance should be declared by its recommended INN. Accompanied by its salt or hydrate form if relevant.

Composition:

Each mL contains:

Alpha Beta Arteether	75 mg
Sterile Oily Base	q.s

(b) Quantitative Declaration, the quantity of the active substance must be expressed per dosage unit

S. No.	Name of ingredients	Spec.	Label claim/3mL	Overage/Factor	Qty/3mL
1	Alpha Beta Arteether	IHS	225 mg	2%	229.5 mg

3. Pharmaceutical Form Visual description of the appearance of the product (colour, markings, etc.) e.g.: Yellow colour oily solution filled in amber glass ampoule.

4. Clinical Particulars,

4.1 Therapeutic Indications:

Alpha Beta 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.

4.2 Posology and method of administration:

Alpha Beta Arteether is for intramuscular use:
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.
Adult: 150 mg once daily administrated I.M for 3 Consecutive days.
Children: 3 mg/kg once daily administered I.M for 3 Consecutive days.

4.3 Contraindications:

Alpha Beta Arteether injection is contraindicated in patients hypersensitive to artemisinin derivatives.

4.4 Special warning and precautions for use:

Before using Alpha Beta Arteether Injection, inform your doctor about your current list of medications, over the counter products (e.g. vitamins, herbal supplements, etc.), allergies, pre-existing diseases, and current health conditions (e.g. pregnancy, upcoming surgery, etc.). Some health conditions may make you more susceptible to the side-effects of the drug. Take as directed by your doctor or follow the direction printed on the product insert. Dosage is based on your condition. Tell your doctor if your condition persists or worsens. Important counseling points are listed below.

- Consult your doctor immediately if your symptoms do not improve, you are unable
- to eat, or you develop fainting, flu-like symptoms, or change in heartbeat
- Do not drive or operate machinery
- Do not stop medication
- Finish the entire course of treatment as prescribed
- Inform your doctor if you have existing medical problems including heart problems
- or HIV
- Inform your doctor of all your other medications

4.5 Interaction with other medicinal products and other forms of interactions:

If you use other drugs or over the counter products at the same time, the effects of Alpha Beta Arteether Injection may change. This may increase your risk for side-effects or cause
your drug not to work properly. Tell your doctor about all the drugs, vitamins, and herbal supplements you are using, so that you doctor can help you prevent or manage drug interactions. Alpha Beta Arteether Injection may interact with the following drugs and products:

- Amiodarone
- Astemizole
- Bretylium
- Disopyramide
- Erythromycin
- Halofantrine

4.6 Fertility, 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. Lactation: It is not known whether Alpha Beta Arteether

is secreted in human milk. Caution should be exercised when Alpha Beta Arteether injection used in lactating mother.

4.7 Effects on ability To Drive and use Machines

There have been no studies to investigate the effect of Alpha Beta Arteether on driving performance or the ability to operate machinery. 4.8 Undesirable Effects While neurotoxicity has been reported in experimental animals, there is no evidence of neurotoxicity in human beings with artemisinin derivatives. Alpha Beta Arteether is usually well tolerated. However, nausea,dizziness and depressed GIT activity can occur. Clinical, neurological, electrocardiographic and biochemical monitoring did not reveal significanttoxicity. Apart from some increase in eosinophil numbers, no haematological abnormality was seen.

4.6 Overdose:

The pre-clinical studies of ά-β Arteether have shown that LD50 value is more than 1000 mg/kg, whereas the maximum dose injected in adults is about 2.5 mg/kg per day. This confirms that the safety window for the dose administered is very wide. Hence this study concludes that ά-β Arteether is well tolerated even when overdose is administered.

5. Pharmacological Properties

5.1 Pharmacodynamic Properties:

Alpha Beta 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 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 the ethyl ether derivative of artemisinin. Main metabolite of Alpha Beta Arteether is Dihydroartemisinin.The half life of Dihydroartemisinin is more than 20 hours. The eliminationof the drug is through hepatic metabolism and gets eliminated at a low rate as compared to other artemisinin derivatives

5.3 Preclinical Safety Data:

One hundred thirty-eight adult patients with acute Plasmodium falciparum malaria were randomized to receive either beta-Arteether or alpha/beta- Arteether. The drugs were administered in the dose of 150 mg once a day intramuscularly for three consecutive days in hospitalized patients. After one week of hospitalization, patients were followed-up for three weeks after release from the hospital. There was no statistically significant difference between cure rates, mean fever clearance time (FCT), mean parasite clearance time (PCT), and occurrence of side effects in either group.

6.0 Pharmaceutical Particulars

(a) List of excipients:

Sr. No.	Name of the Materials	Specification
1	Ethyl Oleate	B.P.
2	Benzyl Alcohal	B.P.
3	Butylated Hydroxy toluen	B.P.
4	Butylated Hydroxy Anisole	B.P.
5	Propyl Gallate	B.P.

(b) Incompatibilities:
None Known.

(c) Shelf life: 36 Months

(d) Special precautions for storage:
Store protected from light and moisture below 30°C.

(e) Nature and contents of container:
Amber glass ampoule.

f) Instructions for use and handling
Not applicable

7.0 Marketing Authorization Holder

Name **:** Fexona Pharmaceutical Co., Ltd

Address **:** 19, Akinlawon Street, Ijesha – Surulere
Lagos – Nigeria.

Phone **:** +2348032587764

E-mail **:** fexonapharmltd@yahoo.com

8.0 Marketing Authorization Numbers

Not applicable

9.0 Date of first authorization/renewal of the authorization

Not applicable

10.0 Date of revision of the text

24/11/2023