1. Name of the Medicinal Product

(a) Product Name : FEXOMAL INJECTION
(b) Strength : 75 mg/ml
(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:
Arteether 75 mg
Sterile Oily Base q.s

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

Ingredient	Spec.	Claim	Overages	Qty./ ml	Functions
Active Ingredient					
Alpha Beta Arteether	I.H.	75 mg	2.0%	76.50 mg	Antimalarial
Inactive Ingredient					
Ethyl Oleate	B.P.	---	---	14.633 mg	Solvent
Benzyl Alcohol	B.P.	---	---	17.000 mg	Preservative
Butylated Hydroxy Toluene	B.P.	---	---	60.800 mg	Antioxidant
Butylated Hydroxy Anisole	B.P.	---	---	0.666 mg	Antioxidant
Propyl Gallate	B.P.	---	---	16.000 mg	Antioxidant

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:
Fexomal Injection (Alpha Beta Arteether Injection 75 mg/ml) 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:
Fexomal Injection (Alpha Beta Arteether Injection 75 mg/ml) 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.

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.

Method of administration:
Fexomal Injection (Alpha Beta Arteether Injection) is for intramuscular use only.

4.3 Contraindications:
Hypersensitivity to the Arteether or to any of the excipients listed in section 6.1.

Fexomal Injection (Alpha Beta Arteether Injection 75 mg/ml) is contraindicated in patients hypersensitive to artemisinin derivatives.

4.4 Special warning and precautions for use:
Before using Fexomal Injection (Alpha Beta Arteether Injection 75 mg/ml), 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 Fexomal Injection (Alpha Beta Arteether Injection 75 mg/ml) 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. Fexomal Injection (Alpha Beta Arteether Injection 75 mg/ml) may interact with the following drugs and products:

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

4.6 Pregnancy and Lactation:

Pregnancy

Use of arteether in pregnant women is not recommended unless absolutely necessary. The effect of arteether on pregnancy is not clearly established and hence should be used only in life-threatening situations.

Breastfeeding

Use of arteether while breastfeeding is not recommended unless necessary. Your doctor will determine whether or not to use arteether.

4.7 Effects on ability to drive and use machine:

No studies on the effects on the ability to drive and use machines have been performed.

4.8 Undesirable effects:

Some possible side effects for Arteether:

- Headache
- Nausea or Vomiting
- Persistent cough
- Dizziness
- Body pain
- Pain at the injection site
- Stomach discomfort and pain
- Chills and rigor
- Watery diarrhea
- Unusual tiredness and weakness
- Low WBC and Platelet count
- Swelling of the liver

4.9 Overdose

No case of overdose has been reported.

5 Pharmacological Properties

5.1 Pharmacodynamic Properties: General Pharmacodynamic Effect

Pharmacotherapeutic group: Antimalarial; ATC code: P01BE04

Mechanism of action
Alpha-Beta Arteether is a fast acting blood schizonticidal agent for P. falciparum malaria at the erythrocytic stage. Alpha-Beta 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:

Absorption and bioavailability
Arteether is the ethyl ether derivative of artemisinin. It absorbed from the the site of injection

Distribution
The half life of Dihydroartemisinin is more than 20 hours.

Metabolism
Main metabolite of Alpha-Beta Arteether is Dihydroartemisinin.

Elimination
The elimination of the drug is through hepatic metabolism and gets eliminated at a low rate as compared to other artemisinin derivatives.

5.3 Preclinical Safety Data:

Nonclinical data reveal no special hazard for humans based on studies of safety pharmacology, genotoxicity and toxicity to reproduction.

Carcinogenicity studies have not been conducted with Fexomal Injection (Alpha Beta Arteether Injection 75 mg/ml) or its components.

6.0 Pharmaceutical Particulars

6.1 List of excipients:

Sr. No.	Name of the Materials	Specification
1	Ethyl Oleate	B.P.
2	Benzyl Alcohol	B.P.
3	Butylated Hydroxy Toluene	B.P.
4	Butylated Hydroxy Anisole	B.P.

6.2 Incompatibilities:

Not applicable.

6.3 Shelf life:

The shelf of Fexomal Injection (Alpha Beta Arteether Injection 75 mg/ml) from the date of manufacture is 36 Months.

6.4 Special precautions for storage:
Store protected from light and moisture at a temperature below 30°C. Keep medicine out of reach of children.

6.5 Nature and contents of container:
Yellow colour oily solution filled in amber glass ampoule of 2 ml.

6.6 Special precautions for disposal and other handling
Any unused medicinal product or waste material should be disposed of in accordance with local requirements.

7.0 Applicant/Manufacturer

Name	**: ZEE LABORATORIES LIMITED**
Address	**: Behind 47, Industrial Area, Paonta Sahib-173025 (INDIA)**
Phone	**: 91-1704-265132**
Fax	**: 91-1704-265135**
E-mail	**: info@zeelab.co.in**