**1. NAME OF THE MEDICINAL PRODUCT**

**1.1 Brand Name :** MALUNO

**1.2 Generic Name :** α -β Arteether Injection 75 mg/ml

**1.3 Strength :** 75 mg

**1.4 Pharmaceutical Form:** Injection

**2. QUALITATIVE AND QUANTITATIVE COMPOSITION**

Each ml contains:

α -β Arteether.....75mg

Arachis Oil BP .....q.s

| No. | Ingredients | Spec. | Claim | Quantity/2ml | Functionality |
|---|---|---|---|---|---|
| 1. | Alpha beta Arteether | IH | 75 mg/ml | 161.11 mg* | Active Pharmaceuical Ingredient |
| 2. | Butylated Hydroxy Anisole | BP | -- | 0.2 mg | Antioxidant |
| 3. | Arachis Oil | BP | -- | 1.6 ml | Vehicle |
| 4. | Benzyl Alcohol | BP | -- | 0.08 ml | Co-Solubilizer |
| 5. | Arachis Oil | BP | -- | 0.3 ml# | Vehicle |
| 6. | Butylated Hydroxy Toluene | BP | -- | 0.2 mg | Antioxidant |

**3. PHARMACEUTICAL FORM:**

Pale yellow coloured liquid filled in amber colour glass ampoule with white ring on neck.

**4. CLINICAL PARTICULARS**

**4.1 THERAPEUTIC INDICATIONS:**

Acute Malaria

Acute uncomplicated multi-drug resistant falciparum malaria

Severe malaria

**4.2 POSOLOGY AND METHOD OF ADMINISTRATION**

Adult : Intramuscular injection 150mg, daily for 3 consecutive days.

Children : Intramuscular injection of 3mg arteether/kg body weight daily for 3 consecutive days.

**4.3 CONTRAINDICATIONS**

α -β Arteether injection is contraindicated during pregnancy and lactation.

**4.4 SPECIAL WARNINGS AND PRECAUTIONS FOR USE**

The product must be used only via the intramuscular route. The use of tuberculin syringes is recommended for administration, particularly in young children.

The loading dose should be equally divided and injected anteriorly into both thighs with each subsequent dose injected into alternating thighs.

Severe falciparum infections may require supportive treatment such as glucose–salt infusion and the use of antipyretics.

The use of α -β Arteether for the treatment of severe malaria in patients with pre-existing renal or liver failure has not been studied.

The potential of α-β Arteether to produce neurotoxity has been observed in animal studies.

In general α -β Arteether shows no tendency to cause QTc prolongation at the recommended dose regimens. QTc prolongation may incidentally occur in patients with pre-existing abnormal ECG.

**4.5 INTERATION WITH OTHER MEDICINAL PRODUCTS AND OTHER FORMS OF INTERACTIONS**

Avoid using with drugs that prolong QT interval.

**4.6 PREGNANCY AND LACTATION**

α -β Arteether injection during Pregnancy is not established. The World Health Organization currently advises against the use of α -β Arteether in the first trimester of pregnancy, unless in a lifesaving situation where other drugs are not suitable. In the second and third trimesters of pregnancy, α -β Arteether and its derivatives are not recommended unless alternative drug treatments are unsuitable.

**4.7 EFFECTS ON ABILITY TO DRIVE AND USE MACHINE**

Patients receiving should be warned that dizziness may occur in which case they should not drive or use machines.

**4.8 UNDESIRABLE EFFECTS**

Nausea, Cough, Dizziness, Body ache, General weakness, Vomiting, Pain at injection site, Abdominal pain, Leg pain, Chills and watery diarrhoea.

**4.9 OVERDOSE**

Give supportive measures and symptomatic treatment.

**5. PHARMACOLOGICAL PROPERTIES**

**5.1 PHARMACODYNAMICS PROPERTIES**

α -β Arteether is fast acting blood schizonticidal agent for P. falciparum malaria at the erythrocytic stage. Arteether is concentrated in parasitized erythroctytes.

The functional group responsible for antimalarial activity of α -β Arteether is endoperoxide bridge. The researchers believe that iron from the digested haemoglobin of the parasite's victim reduces this bridge releasing a highly reactive free radical ion (IV) oxo species which rips apart the parasitic cells.

**5.2 PHARMACOKINETIC PROPERTIES**

After intramuscular injection, both drugs are released slowly into the systemic circulation. Peak plasma concentrations are generally attained between 3-12 hrs. following drug administration.

As the physiochemical properties of the arteether exclude intravenous administration in humans, it is not possible to determine the bioavailabilty, the clearing or distribution following drug

administration.
Plasma protein binding of the drugs is high, 98-99%.
Prior to excretion, the majority of α -β Arteether is metabolized. The most important route is an oxidative dealkylation by CYP3A4 to dihydroartemisinin and the biliary excretion of glucronidated dihydroartemisinin with the faeces. A minor part (20-30%) may be excreted in the urine as dihydroartemisinin glucoronidine.

**5.3 PRECLINICAL SAFETY DATA**

Not applicable

**6.0 PHARMACEUTICAL PARTICULARS**

**6.1 LIST OF EXCIPIENTS**

| **Excipients** | **Specification** |
|---|---|
| Butylated Hydroxy Anisole | BP |
| Arachis Oil | BP |
| Benzyl Alcohol | BP |
| Butylated Hydroxy Toluene | BP |

**6.2 INCOMPATIBILITIES**

Not applicable.

**6.3 SHELF LIFE**

30 Months

**6.4 SPECIAL PRECAUTIONS FOR STORAGE**

Store below 30°C. Protect from light and moisture. Do not freeze.
Keep out of reach of children.

**6.5 NATURE AND CONTENTS OF CONTAINER**

Tray of 3 x 2ml ampoules packed in Mono Carton along with Insert.

**6.6 SPECIAL PRECAUTION FOR DISPOSAL**

Not Applicable

## 7. MARKETING AUTHORIZATION HOLDER

| | | |
|---|---|---|
| Name | : | UNOSOURCE PHARMA NIGERIA LIMITED, |
| Address | : | # 47 Babapomile Street, Onipetesi Estate, Mangoro-Lagos, Nigeria. |
| Phone | : | 002348038540440<br>002348129126660 |
| E-mail | : | bennaworeogbokor@yahoo.com |

## NAME AND ADDRESS OF THE MANUFACTURER

| | | |
|---|---|---|
| Name | : | Akums Drugs & Pharmaceuticals Ltd. |
| Address | : | 2,3,4 & 5 Sector 6B, IIE, SIDCUL, Ranipur, Haridwar-249403, Uttarakhand, India. |
| Phone | : | +91-1334-325982 |