



**National Agency for Food & Drug Administration &  
Control (NAFDAC)**

**Registration & Regulatory Affairs (R & R)  
Directorate**

**SUMMARY OF PRODUCT CHARACTERISTICS  
(SmPC) TEMPLATE**

**1. NAME OF THE MEDICINAL PRODUCT**

EMAZA

**2. QUALITATIVE AND QUANTITATIVE COMPOSITION**

Batch size:50 ltr

			<b>Label Claim</b>	<b>Qty/ Batch</b>	<b>Reason for inclusion</b>
<b>SR. No</b>	<b>Ingredients</b>	<b>Specifi cation</b>			
1	$\alpha$ - $\beta$ Arteether	IHS	150 mg	3.75 kg	Active
2.	Arachis oil	BP	q.s. to 2 ml	q.s. to 50 ltr.	Vehicle

**3. PHARMACEUTICAL FORM**

Injection.

FOR I.M. USE ONLY

## **4. Clinical particulars**

### **4.1 Therapeutic 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.

### **4.2 Posology and method of 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 administered I.M. for 3 consecutive days. Children: 3 mg/kg once daily administered I.M. for 3 consecutive days.

### **4.3 Contraindications**

Arteether is contraindicated in patients showing hypersensitivity to artemisinin derivatives.

### **4.4 Special warnings and precautions for use**

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

### **4.5 Interaction with other medicinal products and other forms of interaction**

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

### **4.6 Pregnancy and 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.

### **Effects on ability to drive and use machines**

patients should be informed that rarely some people experience drowsiness, which may affect their ability to drive or use machines.

### **4.7 Undesirable 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.

#### **4.8 Overdose**

Medical monitoring of the patient is to be continued after emergency treatment.

### **5 PHARMACOLOGICAL PROPERTIES**

#### **5.1 Pharmacodynamics properties**

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 activity of Arteether), releasing a highly reactive free radical iron(IV) oxo species, which alkylates 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**

#### **6.1 List of excipients**

**Arachis oil      BP      q.s. to 2 ml**

#### **6.2 Incompatibilities**

Not Applicable

#### **6.3 Shelf life**

36 months from the date of manufacturing

#### **6.4 Special precautions for storage**

Store below 30° C.

Store in the original package to protect from moisture.

**6.5 Nature and contents of container <and special equipment for use, administration or implantation>**

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

**6.6 Special precautions for disposal <and other handling>**

No special requirements

**7 <APPLICANT/MANUFACTURER>**

MEDICROWN NIGERIA LTD.

7,LLARO ROAD, OFF AIRPORT ROAD, SABON GARI, KANO STATE, NIGERIA