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

ZEDMAL (α-β ARTEETHER INJECTION 150mg/2ml)

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Batch size: 50 ltr			**Label Claim**	**Qty/ Batch**	**Reason for inclusion**
SR. No	**Ingredients**	**Specification**			
1	α-β 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 ofadministration

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.

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 responsiblefor antimalarial activity of 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

6.1 List of excipients

Arachis oil BP q.s. to 2 ml

6.2 Incompatibilities

Not Applicable

6.3 Shelf life

24 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>

ZMC International Ltd
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