1. NAME OF THE MEDICINAL PRODUCT

ADMAL (α-β ARTEETHER INJECTION 150MG/2ML)

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 2 ml Ampoule Contains:
Alpha Beta Arteether…… 150 mg
Arachis Oil BP q. s.
Excipient Qs

Formula:

Sr. No.	Ingredients	Specification	Label Claim (Mg)	Overages %	Standard Quantity For 100 Liters (kg)
1	Alpha Beta Arteether	In-House	150 MG	5%	7.876 kg
2	Benzyl alcohol	BP			2.0 Lits
3	Butylated Hydroxy Anisole	BP			50.0 gm
4	Arachis Oil	BP			QS to 100 L

3. PHARMACEUTICAL FORM

Oily Solution for Injection

4. Clinical particulars

4.1 Therapeutic indications
Severe malaria including cerebral malaria and as a second line drug in chloroquine resistant malaria cases only.

4.2 Posology and method of administration

Posology
ADMAL (α-β ARTEETHER INJECTION 150MG/2ML) is for intramuscular use only. Children - 3mg/Kg per day administered by intramuscular injection over a 3-day period.
The injection must be given under aseptic conditions, deep intramuscularly in the upper lateral quadrant of the buttock. No other drug should be mixed in the same syringe

Method of administration: Intramuscular Route.

4.3 Contraindications
ADMAL (α-β ARTEETHER INJECTION 150MG/2ML) is contraindicated in patients hypersensitive to artemisinin derivatives.

4.4 Special warnings and precautions for use
When treating children, particular care should be taken to ensure the correct doses are given and retained.

4.5 Interaction with other medicinal products and other forms of interaction
ADMAL (α-β ARTEETHER INJECTION 150MG/2ML) prolonged QT interval has been reported in some studies with high dosage of artemisinin derivatives. The cardiac effects of artemisinin are not very important from a clinical point of view, except that caution should be exercised against combinations with other drugs that prolong the QT interval, such as quinine and halofantrine.

4.6 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 α-β Arteether is secreted in human milk. Caution should be exercised when α-β 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 α-β Arteether on driving performance or the ability to operate machinery.

4.8 Undesirable effects

ADMAL (α-β ARTEETHER INJECTION 150MG/2ML) has below undesirable effect,
While neurotoxicity has been reported in experimental animals, there is no evidence of neurotoxicity in human beings with artemisinin derivatives. α-β Arteether is usually well tolerated. However, nausea, dizziness and depressed GIT activity can occur. Clinical, neurological, electrocardiographic and biochemical monitoring did not reveal significant toxicity. Apart from some increase in eosinophil numbers, no Haematological abnormality was seen.

4.9 Overdose

Overdose treatment should be symptomatic and supportive.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamics properties

Pharmacotherapeutic group: Antimalarial

ATC code: P01BE02

α-β Arteether is a fast acting blood schizonticidal agent for P. falciparum malaria at the erythrocytic stage. α-β Arteether is concentrated in parasitized erythrocytes. The functional group responsible for antimalarial activity of α-β Arteether is Endoperoxide Bridge. Iron from the digested haemoglobin of the parasite's victim reduces this bridge, releasing a highly reactive free radical iron species which causes lysis of the parasitic cell. It is also proposed that α-β Arteether inhibits the protein synthesis and alters the ribosomal organization and endoplasmic reticulum.

5.2 Pharmacokinetic properties

α-β Arteether is transformed into dihydroartemisinin. It has a half life of 20 hours. It is eliminated by hepatic metabolism. The elimination is much slower compared to other artemisinin compounds.

5.3 Preclinical safety data

Not Applicable

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

1. Arachis oil….. BP
2. Benzyl Alcohol…BP
3. Butylated Hydroxy Anisole….BP

6.2 Incompatibilities

None

6.3 Shelf life

36 Months

6.4 Special precautions for storage

Store below 30°C. Protect from light.

6.5 Nature and contents of container <and special equipment for use, administration orimplantation>

Each box Contains:
2 ML USP TYPE 1 FLINT GLASS AMPOULES
α-β arteether injection 150 mg/2 ml is filled in 2 ml USP type 1 flint glass ampoules. 3 filled ampoules is labelled and packed in Monocarton with leaflet.

6.6 Special precautions for disposal <and other handling>

No special requirements

7. <APPLICANT/MANUFACTURER>

Ciron Drugs & Pharmaceuticals Pvt. Ltd.
C- 1101/1102, Lotus Corporate Park,
Graham Firth Steel Compound,
Jay Coach Junction, Western Express Highway,
Goregaon (East) Mumbai,
Maharashtra, India – 400063