SUMMARY OF PRODUCT CHARACTERISTICS

1. Name of the Medical Product
Artemether 40mg/0.5mLInjection

2. Quality and Quantitative Composition

Composition	Quantity/ampoule
Artemether	40mg
Peanut oil	0.5ml

3. Pharmaceutical Form Visual Description
A colorless or yellowish clear oily solution

4. Clinical Particulars
4.1 Therapeutic indications
Antimalarial drug. For the treatment of malaria due to *P. falciparum* and the first aid of critical malaria, or when resistance to other antimalarials is suspected.

4.2 Posology and method of administration
The drug is used for intramuscular injection.
Adults:
Five days course with the initial dose of 3.2mg/kg on day one, followed by 1.6mg/kg for the next 4 days. The initial dose for adults is 160mg (2 ampoules each containing 80mg artemether), followed by 80mg (1 ampoule containing 80mg artemether) each time from the 2^{nd} to the 5^{th}day.The dose for overweight patients should be increased on the basis of the individual weight or under the doctor's prescription.
Children:
Five days course with the initial dose of 3.2 mg/kg on day one, followed by 1.6 mg/kg for the next 4 days.

4.3 Contraindications
Contraindicated in the patients allergic to artemether and peanut oil. The Artemether Injection should not be used in pregnant woman of the first trimester except the doctor condiders that it is necessary.

4.4 Special warning and precautions
In case of freeze due to coldness, please warm it before use.

4.5 Interaction with other medical products and other forms of interactions
Studies and reviews in the literature demonstrated that the active substance of Artemether had no interactions with other drugs on decreasing therapeutic effects and increasing toxic and side effects in bodies.

4.6 Pregnancy and lactation
It should be used with caution in the first trimester of pregnancy since some fetus absorption has been observed.

4.7 Effect and ability to drive and use machine
No such study has been conducted yet

4.8 Undesirable effects
Clinical dosage exhibits slight adverse reactions. A transient low fever and reticulocytopenia may occur in individual cases. Slight rise of SGOT and SGPT may occur in individual cases. Arrhythmia may occur in rare cases (such as ventricular tachycardia).

4.9 Overdose
Although no case of overdose has been documented, in case of accident, symptomatic treatment is recommended under the instruction of doctors.

5. Pharmacological Properties
5.1 **Pharmacodynamic properties**
Animal pharmacodynamics showed that the drug is a strong schizonticide. Parasitemia clearance occurs rapidly with stable efficacy after administration. It is also effective against chloroquine-resistant *P. falciparum* malaria.

5.2 **Pharmacokinetic properties**
The drug is absorbed rapidly and completely after i.m. injection. The maximum blood concentration of the drug is observed in about 7 hours after i.m. injection of 10mg/kg in human body. The peak value is about 0.8μg/ml with the plasma half-life of about 13 hours. It is widely distributed in the body with the highest level found in the brain and followed by liver and kidney. It is mainly excreted in the feces with a part in urine.

5.3 **Preclinical safety data**
Acute toxicity studies on animals showed that the LD_{50} of Artemether in mice of a single i.g. administration is 895mg/kg and a single i.m. injection is 296mg/kg; in rats, the LD_{50} of a single i.m. injection is 597mg/kg. This proves the toxicity of Artemether is quite low.

6. Pharmaceutical Particulars
6.1 List of excipients
Peanut oil

6.2 Incompatibilities
Not applicable

6.3 Shelf life
48 months (4 years)

6.4 Special precautions for storage
Store in well closed container at room temperature below 30℃ and protected from light.

6.5 Nature and contents of containers
In glass ampoules, 6 ampoules in one small paper box and 300 boxes per carton

7. Marketing Authorization Holder
KPC Pharmaceuticals, Inc.
BuAddress: No.166, Keyi Road, High and New Technology Development Zone, Kunming, Yunnan Province, P.R.China
Tel: +86-871-68311225
Fax: +86-871-68256814
E-mail: registry@kpc-cotec.com

8. Marking Authorization number
08373/08521/REN/2022

9. Renewal of the Authorization
13-January-2023

10. Date of revision of the text
28-June 2023