

SUMMARY OF PRODUCT CHARACTERISTICS

1. Name of the Medical Product

Artemether Injection 80mg

2. Quality and Quantitative Composition

Composition	Quantity/ampoule
Artemether	80mg
Peanut oil	1 mL

3. Pharmaceutical Form

Solution for Injection

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 2nd to the 5th 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 considers 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 LD₅₀ 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 LD₅₀ 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°C 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.

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8. Marking Authorization number

04763/06929/REN/2019

9. Renewal of the Authorization

21-November-2019

10. Date of revision of the text

27-June- 2023