

1.2.12 Certificate of Registration and Retention of Premises

-N/A-

1.2.13 Evidence of Previous Market Authorization (if Applicable)

-N/A-

1.2.14 Invitation letter for GMP inspection

-N/A-

1.3 Product Information

1.3.1 Summary Of Product Characteristics

1. Name of the medicinal product

Artemether Injection 80mg/1ml

2. Qualitative and quantitative composition

Each 1ml ampoule contains Artemether equivalent to 80mg of the anhydrous substance.

RAW MATERIAL	LABEL CLAIM PER AMPOULE	QUANTITY PER BATCH
Artemether	80mg	800g
Benzyl alcohol	20mg	200g
Soybean oil	To 1ml	To 10000ml

3. Pharmaceutical form :

Clear solution for I.M administration.

4. Clinical particulars

4.1 Therapeutic indications

Applicable to all types of malaria, but mainly for emergency treatment of chloroquine resistant falciparum and severe falciparum malaria.

4.2 Posology and method of administration

Artemether is a derivative of artemisinin, which has a strong and rapid killing effect on the red stage of Plasmodium, and can quickly control clinical onset and symptoms.

The mechanism of action of artemisinin is not well understood, mainly to interfere with the membrane-mitochondrial function of Plasmodium. Artemisinin changes its

membrane structure by affecting the ultrastructure of the Plasmodium red inner phase. Due to the action on the food membrane, the nutrient uptake of the malaria parasite is blocked, and when the malaria parasite loses a large amount of cytoplasm and nutrients, and is not replenished, it quickly dies. Its mode of action is mediated by its endogenous peroxide (oxygen) bridge, which is mediated by free iron produced by hemoglobin decomposition, producing unstable organic free radicals and/or other electrophilic intermediaries, and then with the malaria parasite. The protein forms a covalent adduct that kills the malaria parasite. The antimalarial activity of artemether is 6 times greater than that of artemisinin.

4.3 Contraindications

-No-

4.4 Special warnings and precautions for use

Adverse Reactions:

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).

Precaution: In case of freeze due to coldness, please warm it before use.

4.5 Interaction with other medicinal products and other forms of interaction

Studies and reviews in the literature demonstrated that the active substance of Artemether had no interactions with other drugs on decreasing therapeutic and increasing toxicity and side effects in human 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 Effects on ability to drive and use machines

No studies on the effects on the ability to drive and use machines have been performed. However, undesirable effects may occur (e.g. allergic reactions, dizziness, convulsions), which may influence the ability to drive and use machines.

4.8 Undesirable effects

This product has a mild response. Individual patients have aspartate aminotransferase, alanine aminotransferase is slightly elevated, and reticulocytes may be transiently reduced.

4.9 Overdose

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

5. Pharmacological properties

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: Antimalarial .

Artemether is a derivative of artemisinin, it has a powerful and rapid killing effect on the erythrocytic stage of plasmodium vivax, can control the clinical seizures and symptoms rapidly. The mechanism of action of artemisinin is not very clear, the main function is to interfere with the surface membrane of plasmodium falciparum, a mitochondrial function. Artemisinin influences the ultrastructure of the erythrocytic stage of plasmodium vivax, changes in its membrane structure. Because of the action of food vacuole, the nutrient intake of plasmodium was blocked. When the plasmodium lost a lot of cytoplasm and nutrients, it could not be supplemented and died quickly. The mode of action is through the endoperoxide bridge (hydrogen peroxide), the free iron hemoglobin produced after mediated, produces unstable organic free radicals and / or other electrophilic mediators, and then form a covalent adduct with the protein of plasmodium, to killed the parasite. The antimalarial activity of artemether was 6 times larger than that of artemisinin.

5.2 Pharmacokinetic properties

After intramuscular injection, the absorption is rapid and complete. After intramuscular injection of 10 mg/kg, blood medicine peak time is 7 hours, the peak value can reach about 0.8mg/L, T_{1/2} is about 13 hours. In the body is widely distributed, with brain tissue at most, liver, kidney next. Mainly through the intestinal excretion, followed by urinary excretion.

5.3 Preclinical safety data

Non-clinical data reveal no special hazard for humans based on studies of safety pharmacology, repeated dose toxicity, genotoxicity and toxicity to reproduction and development.

6. Pharmaceutical particulars

6.1 List of excipients

Benzyl alcohol

Soybean oil

6.2 Incompatibilities

Not applicable

6.3 Shelf life

36 months.

6.4 Special precautions for storage

Store in a cool and dry place. Protect from light.

6.5 Nature and contents of container

Clear glass 1ml ampoules

6.6 Special precautions for disposal and other handling

Protect from light, Any unused medicinal product or waste material should be disposed of in accordance with local requirements.

7. Marketing authorisation holder

Anhui Chengshi Pharmaceutical Co., Ltd (AC Pharmaceutical Co., Ltd.)

8. Marketing authorisation number(s)

- N/A -

9. Date of first authorisation/renewal of the authorization

- N/A -

10. Date of revision of the test

- N/A -

1.3.2 Labelling (outer & inner labels)

-N/A-