



SUMMARY OF PRODUCT CHARACTERISTICS (SmPC)

1-Name of the Medicinal Product : Artemether Injection 80mg/1ml

1.1 Product Name: Artemether Injection

1.2 Strength: 80mg/1ml

1.3 Pharmaceutical Dosage Form: solution for injection

2-Quality and Quantitative Composition :

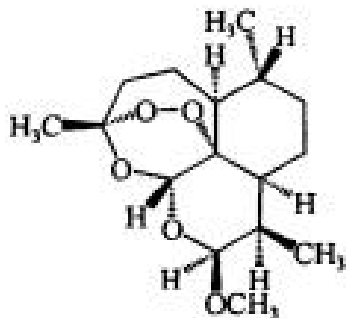
2.1 Qualitative Declaration

The active substance of the Artemether Injection is Artemether.

Artemether: White crystals or crystalline powder, odorless, taste slightly bitter, Very soluble in chloroform or acetone, freely soluble in ethanol or ethyl acetate, practically insoluble in water.

The molecular formula of Artemether: $C_{16}H_{26}O_5$

The structural formula of Artemether :



The molecular weight of Artemether : 298.4

The CAS number of Artemether : 71963-77-4

2.2 Quantitative Declaration

Artemether Injection 80mg/1ml



Dosage form: small volume injection

Concentration: 80mg/1ml

Product description: 1ml of Colorless to light yellow transparent oily liquid is filled in the glass ampoule (1ml) .

Ingredients	Quantity per ampoule (1ml)	Function of ingredients
Artemether	80mg	Active substance
Benzyl alcohol	20 mg	Disinfectant
Refined Soya Oil	1ml	Solvent

3-Pharmaceutical Form :

Dosage form: small volume injection

1ml of Colorless to light yellow transparent oily liquid is filled in the glass ampoule (1ml) .

4-Clinical Particulars

4.1 Therapeutic indications

Applicable to all types of malaria, but mainly used for the treatment of chloroquine falciparum malaria and dangerous falciparum malaria emergency.

4.2 Posology and method of administration

1. Normal dosage for adults, intramuscular injection, the first dose 160mg (2 doses), once a day from the 2nd day, 80mg (1 dose) each time, for 5 days.

2. Normal dosage for children, intramuscular injection, the first dose according to body weight 3.2mg/kg; From the 2nd day to the 5th day, 1.6mg/kg per body weight, once a day.

4.3 Contraindications

It's not clear.

4.4 Special warning and precautions for use

If the product is cold and solidifies, it can be used after mild temperature dissolution.

4.5 Interaction with other medicinal products and other forms of Interactions

This experiment has not been conducted and there are no reliable references



4.6 Pregnancy and lactation

Use with caution in pregnant women.

4.7 Child medication

This experiment has not been conducted and there are no reliable references

4.8 Elderly medication

This experiment has not been conducted and there are no reliable references

4.9 Undesirable effects

The adverse reactions of this product are mild, some patients have mild elevation of aspartate aminotransferase and alanine aminotransferase, and reticulocyte may have transient reduction.

4.10 Overdose

This experiment has not been conducted and there are no reliable references

4.11 Pharmacology and toxicology

1. Pharmacology:

Artemether, a derivative of artemisinin, has a powerful and rapid killing effect on the red stage of plasmodium, and can quickly control the clinical onset and symptoms. The mechanism of action of artemisinin is not clear. It mainly interferes with the membrane - mitochondrial function of plasmodium parasites. Artemisinin changed the membrane structure of plasmodium falciparum by affecting the ultrastructure of the endored stage. Due to the action of the food vesicle, the nutrient uptake of the plasmodium is blocked, and the plasmodium loses a large amount of cytoplasm and nutrients, but can not be replenishment, so it quickly dies. The mechanism of action is the production of unstable organic free radicals and/or other electron-philic mediators via the decomposition of hemoglobin via its internal peroxide (dioxygen) bridge, which then forms covalent admixture with plasmodium proteins and causes plasmodium death. Artemether is six times more active against malaria than artemisinin.

2. Toxicology:

The median lethal dose (LD50) of artemether was 895-977mg /kg for oral administration in mice and 597mg/kg for intramuscular injection of artemether oil in rats. Subacute toxicity test showed that there were no other adverse reactions except decreased reticulocyte after intramuscular administration of artemether oil 18mg/kg for 14 days. This drug has certain embryonic toxicity, manifested as embryonic absorption.

4.4 Pharmacokinetics

Rapid and complete absorption after intramuscular injection. After intramuscular injection of 10mg/kg, the peak time of blood drug reached 7 hours, the peak reached



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about 0.8mg/L, and the half-life ($t_{1/2}$) was about 13 hours. It is widely distributed in the body, mostly in brain tissue, followed by liver and kidney. Excretion is mainly through the intestine, followed by urine excretion.

5-Pharmaceutical Particulars

5.1 Shelf life
36months

5.2 Special precautions for storage
Shading and airtight storage.stored below 20 °C.

6-Marketing Authorization Holder :

Anhui Chengshi Phamaceutical Co., Ltd.
No. 5068 Huaishang road,Bengbu,Anhui province, China

7-Name Of Manufacturer :

Anhui Chengshi Phamaceutical Co., Ltd.
No. 5068 Huaishang road,Bengbu,Anhui province, China

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