

1.3 PRODUCT INFORMATION

1.3.1 Summary of Product Characteristics (SmPC)

1.3.1.1 Name of the product: Artemether Injection 80mg/1ml

1.3.1.2 Qualitative and quantitative composition

Each ampoule (1ml) contains: Artemether 80mg

1.3.1.3 Pharmaceutical form

Liquid Injection . For I.M. use Only.

1.3.1.4 Clinical particulars

Therapeutic indications

Antimalarial drug. For the treatment of all kinds of malaria including the chloroquine-resistant *P. falciparum* malaria and the first aid of critical malaria.

1.3.1.5 Pharmacological Properties

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. 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 597 mg/kg. This proves the toxicity of Artemether is quite low.

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 0.8ug/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 the liver and kidney. It is mainly excreted in the feces with a part in urine.

Usage and Dosage:

The drug is used for intramuscular injection, five days course with the initial dose of 3.2mg/kg, followed by 1.6mg/kg for the following 4 days.

The initial dose for adults is 160mg, (2 ampoules), followed by 80mg (1 ampoule) every time from the 2nd to 5th day. The dose for children or overweight patient should be decreased or increased on the individual weight or under the doctor's prescription.

Administration for Children:

For children, the dose should be chosen as follows:

AGE (year)	WEIGHT	TOTAL DOSE	Day1	Day2	Day3	Day4	Day5
<1	<8kg	75mg	25mg	12.5mg	12.5mg	12.5mg	12.5mg
1-3	8-12.5kg	120mg	40mg	20mg	20mg	20mg	20mg
3-6	12.5-17.5kg	150mg	50mg	25mg	25mg	25mg	25mg
6-9	17.5-25kg	240mg	80mg	40mg	40mg	40mg	40mg
9-12	25-32kg	300mg	100mg	50mg	50mg	50mg	50mg
12-16	32-47kg	360mg	120mg	60mg	60mg	60mg	60mg

Contraindications: No.

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

Drug Interactions:

Studies and reviews in the literature demonstrated that the active substance of Artemether had no interaction with other drugs on decreasing therapeutic effects and increasing toxicity and side effects in human bodies.

Pregnancy and Lactation:

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

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 case (such as ventricular tachycardia).

Overdose:

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

1.3.1.6 Pharmaceutical particulars

1.3.1.6.1 List of excipients

Tea-seed oil.

1.3.1.6.2 Incompatibilities

Not applicable.

1.3.1.6.3 Shelf life

36 months

1.3.1.6.4 Special precautions for storage

Store at temperature not exceeding 25°C. Protect from light and moisture. Keep out of reach of Children.

1.3.1.6.5 Nature and contents of container

1ml clear glass ampoules, 6 ampoules in a box.

1.3.1.6.6 Special precautions for disposal and other handling

Not applicable.

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