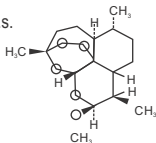


Artemeter 20-40-80

Artemether Injection 20-40-80 mg/1 mL

Each 1 ml ampoule contains:

Artemether 20 mg
Ethyl Oleate B.P. q.s.
(Oily base)



Molecular Weight + 298.4

Molecular formula C₁₆H₂₆O₅ =

Description: Clear, colorless or yellow oily solution

Pharmacology and Toxicology:

Pharmacodynamics in animals show that the drug is a strong schizonticide. Systemic clearance occurs rapidly with stable efficacy after administration. It is also effective against *P. falciparum* malaria (Chloquin and Presdint).

Acute toxicity studies in animals showed that the Ld₅₀ of Artemether in rats from a single I.V. administration is 895 mg/kg and from a single I.M. injection is 296 mg/kg. This proves that the toxicity of artemisinin is quite low.

Pharmacokinetics:

The drug is rapidly and completely absorbed after I.M. injection. The maximum concentration of the drug in the blood is observed approximately 7 hours after I.M. injection of 10 mg/kg into the human body. The peak value is approximately 0.08 mg/ml with a plasma half-life of approximately 13 hours. It is widely distributed throughout the body, most commonly found in the brain, followed by the liver and kidneys. It is primarily excreted in the stool, with a portion in the urine.

Indication:

Antimalarial drug. For the treatment of all types of malaria, including chloroquine-resistant *P. falciparum* and *Plasmodium vivax* malaria.

Use and Dosage:

The drug is for intramuscular injection, a 5-day course with an initial dose of 3.2 mg/kg, followed by 1.6 mg/kg for the next 4 days. The initial dose for adults is 160 mg (2 ampoules), followed by 80 mg (1 ampoule) each time from the 2nd to the 5th day. The dose for children or overweight patients should be decreased or increased based on individual weight or as prescribed by a physician.

Adverse effect:

Clinical dosage presents mild adverse reactions. Low-grade fever and transient reticulocytopenia may occur.

may occur in individual cases. A slight increase in SGPT and SGOT levels may occur; rare adverse events (such as ventricular tachycardia) have been reported.

Precautions:

If the product freezes due to cold temperatures, warm it up before use.

Pregnancy and lactation:

Use with caution during the first trimester of pregnancy, as fetal absorption has been observed in some cases.

Pediatric administration:

For children, the dosage should be determined as follows:

AGE (YEARS)	TOTAL WEIGHT	DOSE	DIA1	DIA2	DIA3	DIA4	DIA5
<1	<8 kg	75mg	25mg	12.5mg	12.5mg	12.5mg	12.5mg
1 in 3	8-12kg	120mg	40mg	20mg	20mg	20mg	20mg
3 in 6	12.5-17.5kg	150mg	50mg	25mg	25mg	25mg	25mg
6 in 9	17.5-25kg	240mg	80mg	40mg	40mg	40mg	40mg
9 in 12	25-32kg	200mg	100mg	50mg	50mg	50mg	50mg
12 in 16	32-47kg	350mg	120mg	60mg	60mg	60mg	60mg

The dosage for children should be adjusted based on individual body weight or as prescribed by a physician.

Drug interactions:

Studies and literature reviews have demonstrated that the active substance artemisinin does not interact with other medications in a way that reduces therapeutic effects or increases toxicity and side effects in the human body.

Overdose:

Although no cases of overdose have been documented, in the event of accidental overdose, symptomatic treatment is recommended under medical supervision.

Strength: 1 mL: 20-40-80 mg

Shelf life: Three years

Storage: Store below 25°C and protect from light.

Keep all medicines out of the reach of children.

Manufactured in India:

