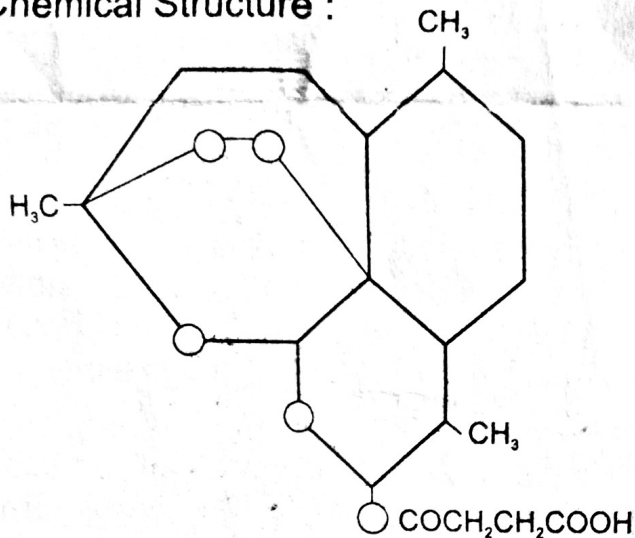


Rx

Artesunate Injection IP

RT-NET INJECTION 60mg/vial

Chemical Structure :



Molecular formula $C_{19}H_{28}O_8=384.42$

COMPOSITION :

Each vial contains:

Artesunate (Sterile) IP 60 mg

The pack contains :

1ml ampoule of

Sodium Bicarbonate Injection IP 5% w/v

5ml ampoule of

Sodium Chloride Injection IP 0.9% w/v

DESCRIPTION :

Artesunate is water soluble hemisuccinate derivative of artemisinin, an antimalarial principle extracted from leaves of the plant *Artemisia annua*. Artemisinin is a sesquiterpene lactone peroxide. It is a white crystalline powder, odourless and almost

tasteless.

The chemical name is Dihydroartemisinin-10-ol hydrogen succinate.

PHARMACOLOGICAL ACTIONS :

ANTIMALARIAL ACTIVITY :

Artemisinin compounds are concentrated in parasitized erythrocytes. Endoperoxide bridge is essential for antimalarial activity. They are thought to cause free radical damage to the parasite membrane system, although the precise mechanism is unclear.

Artemisinin compounds act rapidly stopping parasite development and preventing subsequent cytoadherence.

Clinical effectiveness of artemisinin compounds have been confirmed in *P. vivax* and *P. falciparum* malaria (both in chloroquine sensitive and resistant strains).

Artemisinin compounds are rapidly acting blood schizonticides for these species. They act early in the asexual parasite developmental cycle by destroying the early ring forms. They have no activity on persistent hepatic forms (hypnozoites) and on gametocytes. Their effectiveness in other species of malaria i.e. *P. ovale* and *P. malariae* is yet not fully evaluated.

CLINICAL PHARMACOKINETICS :

Plasma drug concentration decreases rapidly after intravenous administration of artesunate. The plasma half-life is about 30 minutes. It distributes widely throughout the body and with high concentration in intestines, liver and kidneys. Only small quantity is excreted in the urine and in the stools. It is mainly eliminated by metabolic

biotransformation.

INDICATIONS :

For use in severe malaria including cerebral malaria and as a second line treatment in chloroquine resistant malaria. Not to be used as a first line treatment of malaria.

DOSAGE AND ADMINISTRATION :

Falcinova injections are for intravenous or intramuscular use.

The usual dose of artesunate is 60mg daily. The first dose is doubled. The recommended dose in children is 1.2mg/kg. The usual duration of the treatment is 5 days. The duration of treatment is 7days in very serious and non-immune patients. If the patient is infected with high parasitaemia (RBC infection > 10%) an additional dose of 60mg should be given after 4-6 hours of first dose of 120mg.

The recrudescence rate is <10% in chloroquine resistant areas.

Before administration, artesunate powder is mixed with 1ml of 5% sodium bicarbonate and shaken for 2-3 minutes. After it dissolves completely and solution becomes clear, air is eliminated from the vial with a syringe and needle.

For IV use, add 5ml (and for IM use, add 2ml) of 5% dextrose or normal saline to make final concentration of 10mg/ml of artesunate (IM 20mg/ml).

For IV use, the required amount of drug is administered slowly at a rate of 3-4ml/minute.

It should be injected immediately after the

powder of artesunate dissolves. If the solution appears cloudy or sediment occurs, it should not be used. It should not be used as an intravenous infusion.

PRECAUTIONS :

The results of animal experiments have shown some embryotoxic effect. Therefore, it should be used with extreme caution in pregnancy within the first three months.

ADVERSE REACTIONS :

No adverse reactions have been observed with the recommended dose till now. Transient reticulocytopenia may occur when dose in excess of 3.75mg/kg is given.

PRESENTATION :

Vial pack with 1ml ampoule of Sodium Bicarbonate Injection IP 5% w/v & 5ml ampoule of Sodium Chloride Injection IP 0.9% w/v

KEEP IN A COOL PLACE

PROTECT FROM LIGHT



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