For the use of a Registered Medical Practitioner or a Hospital or a Laboratory only.

Arthemed®

60mg

Artesunate Injection 60mg

I.M. I.V. For intramuscular/ intravenous use

COMPOSITION
Each vial contains :
Artesunate 60mg

The pack contains:
1ml ampoule of Sodium Bicarbonate Injection BP 5% w/v
5ml ampoule of Sodium Chloride Injection BP 0.9% w/v

DESCRIPTION
Artesunate is an antimalarial agent. It is a water-soluble hemisuccinate derivative of artemisinin. Artemisinin is a sesquiterpene lactone isolated from Artemisia annua, a herb that has traditionally been used in China for the treatment of malaria. Artesunate and its active metabolite artemisinin are potent blood schizonticides, active against the ring stage of the parasite. Artesunate is ideal for the treatment of severe malaria, including cerebral malaria. It is also active against chloroquine and mefloquine resistant strains of P. falciparum.
It is unstable in neutral solution and is therefore only available for injections as artesunic acid. The injectable formulation must be prepared immediately before use in 5% (w/v) sodium bicarbonate solution to produce the salt sodium artesunate.

INDICATIONS
Injection - Treatment of severe falciparum malaria in areas where there is evidence of quinine resistance.
Artesunate should not to be used as a first line treatment of malaria.
Artesunate is not recommended for the treatment of malaria caused by P. vivax, P. ovale and P. malariae since other effective antimalarial drugs are available for this purpose.

CONTRAINDICATIONS
The drug is contraindicated in patients with prior hypersensitivity to artesunate or artemisinin derivatives.

CLINICAL PHARMACOLOGY
Artesunate is a potent blood schizonticide agent for P. falciparum. It is effective against P. falciparum resistant to all other antimalarial drugs. It does not have hypnozoiticidal activity. It reduces gametocyte carriage rate.
Artesunate binds tightly to parasitized erythrocyte membranes. The functional group responsible for antimalarial activity of artesunate is endoperoxide bond. Release of an active oxygen species from this bond kills the parasite if accumulated in the erythrocytic cells.
It also suppresses the production or activity of antioxidant enzymes in the erythrocytes, causing lysis of the parasitic cell due to the highly reactive free oxygen radicals.
Artesunate has been reported to clear fever in patients with severe falciparum malaria 16 - 25 hours after parenteral administration.

PHARMACOKINETICS
Pharmacokinetic data in humans are sparse, with no data demonstrating the rate or extent of absorption or the systemic distribution of artesunate. After parenteral administration, artesunate is rapidly hydrolyzed to the active metabolite dihydroartemisinin. The oral formulation is probably hydrolysed completely before entering the systemic circulation. Peak serum levels occur within one hour of an oral dose of artesunate and persist for up to 4 hours. Following intravenous administration, elimination half-life of 45 minutes has been reported. Dihydroartemisinin has a plasma elimination half-life of less than 2 hours, which may slow the development of resistance to artesunate.

DOSAGE AND ADMINISTRATION
Monotherapy : In those situations where the use of artemisinin combinations is impossible, for example because of patient intolerance to mefloquine, monotherapy with artemisinin drugs may be used in regimens of 7 days with every effort being made to ensure compliance. Administration of shorter regimens to non-immunes patients leads to unacceptably high levels of recrudescence.
Dose - 4mg/Kg loading dose on the first day followed by 2mg/Kg once a day for 6 days.
Parenteral therapy :
STEP 1 : The powder for injection should be reconstituted with 1ml of Sodium Bicarbonate injection BP 5% w/v and mix well.
STEP 2 : For I.V. use – Add 5 ml of Sodium Chloride Injection BP 0.9% w/v to the vial. Mix well.
For I.M. use – Add 2 ml of Sodium Chloride Injection BP 0.9% w/v to the vial. Mix well.
STEP 3 : For I.V. use, the required amount of the drug is administered slowly over a period of 3-4 minutes. The powder for Injection is difficult to dissolve and care should be taken to ensure that it is completely dissolved before parenteral administration. It should always be used immediately after reconstitution. If the solution is cloudy or a precipitate is present, the parenteral preparation should be discarded.
Severe malaria : Arthemed is administered at a dose of 2.4 mg of artesunate/kg body weight, by intravenous (IV) or intramuscular (IM) injection at 0,12 and 24 hours, then once daily until oral treatment can be substituted. Arthemed should be administered for a minimum of 24 hours (3 doses), regardless of the patient's ability to tolerate oral medication earlier. After at least 24 hours of Arthemed, and when able to tolerate oral medication, the patient should be switched to a complete treatment course of an oral combination antimalarial regimen.

PRECAUTIONS
Parenteral artesunate should be used for the treatment of severe falciparum malaria only where there is evidence that the antimalarial efficacy of quinine is declining.
USAGE IN PREGNANCY
Little experience has been gained with the use of artesunate in pregnancy, but the parenteral preparation should not be withheld if it is considered life-saving to the mother. Oral artesunate should not be used during the first trimester of pregnancy.

DRUG INTERACTIONS
Artesunate has a minimal effect on hepatic cytochrome P450 activity and does not appear to influence the metabolism of mefloquine, a drug likely to be used in combination with artesunate.
Artersunate does not inhibit the formation of carboxy-primaquine, a metabolite of primaquine.

ADVERSE EFFECTS
Artesunate and other related artemisinin derivatives have been widely used in China, with no reports of any serious adverse reactions. Drug induced fever can occur. Neurotoxicity has been observed in animal studies but not in humans. In view of the uncertainty about toxic effects, caution should be exercised when more than one 3-day treatment is given. Cardiotoxicity has been observed following administration of high doses.
In healthy volunteers, a reversible reduction in reticulocyte counts was the dose limiting adverse effect of artesunate, occurring with doses of 16.88mg/Kg.
Possible drug related adverse effects include dizziness, itching, vomiting, abdominal pain, flatulence, headache, bodyache, diarrhoea, tinnitus and increased hair loss, macular rash, reduction in neutrophil counts and convulsions. However, it is likely that many of these effects are disease-related rather than drug-induced.
Occasional skin rash and pruritus has been observed with artesunate.
There were no clinically important local or systemic adverse effects observed in 346 patients treated with intravenous artesunate. Electrocardiography was undertaken in a total of 82 patients. Slight sinus bradycardia occurred in a few patients and transient first degree atrioventricular block was observed in 1 patient. Slight elevations in hepatic transaminases were also reported, but these were more likely to be related to the disease than to the treatment per se.

OVERDOSAGE
No data available for overdosage of artesunate.

STORAGE:
Store below 30°C. Protect from direct sunlight.

Keep all medicines out of the reach of children.

E/D/PI-4394

PRESENTATION
Artesunate 60mg Powder in 5ml vial alongwith a 1ml ampoule of Sodium Bicarbonate Injection BP 5% w/v and a 5ml ampoule of Sodium Chloride Injection BP 0.9% w/v.

NAFDAC REG. No.: A4-2533

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80mm (L) x145mm (H)

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