GEN-M®
(Artesunate)
for Injection Ph.Int.

30mg
60mg
120mg

جین ایم

DESCRIPTION
Artesunate is an antimalarial agent. It is a water-soluble hemisuccinate derivative of dihydroartemisinin. Artesunate and its active metabolite dihydroartemisinin are potent blood schizontocidal, 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.

COMPOSITION
Gen-M 30mg for Injection
Each vial contains:
Artesunate Ph.Int. 30mg
The pack included;
0.5ml ampoule of sodium bicarbonate injection USP 5% w/v.
2.5ml ampoule of sodium chloride injection USP 0.9% w/v.

Gen-M 60mg for Injection
Each vial contains:
Artesunate Ph.Int. 60mg
The pack included;
1ml ampoule of sodium bicarbonate injection USP 5% w/v.
5ml ampoule of sodium chloride injection USP 0.9% w/v.

Gen-M 120mg for Injection
Each vial contains:
Artesunate Ph.Int. 120mg
The pack included;
2ml ampoule of sodium bicarbonate injection USP 5% w/v.
10ml ampoule of sodium chloride injection USP 0.9% w/v.

CLINICAL PHARMACOLOGY
Artesunate is a potent blood schizontocidal 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 endopar parenteral oxide 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. After parenteral administration, artesunate is rapidly hydrolyzed to the active metabolite dihydroartemisinin. On 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.

INDICATIONS:
Treatment of severe falciparum malaria in areas where there is evidence of quinine resistance.

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

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: 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. Artesunate 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. In view of the uncertainty about toxic effects, caution should be exercised when more than 3 days 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, body ache, 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.

DOSAGE AND ADMINISTRATION:
Severe malaria:
Dose: 2.4mg/Kg at 0, 12 and 24 hours then 2.4mg/Kg daily for upto 7 days.

Reconstitution Method
Gen-M 30mg for Injecton:
Step 1: Add 0.5ml Sodium Bicarbonate Inj. 5% in vial & mix well until clear solution.
Step 2: For I.V use: Add 2.5ml Sodium Chloride Inj. 0.9% in vial (Step 1) & mix well & use by slow I.V route over 2-3 minutes (Do not put solution in I.V drip).
For I.M use: Add 1ml Sodium Chloride Inj. 0.9% in vial (Step 1) & mix again & use by I.M route.

Gen-M 60mg for Injecton:
Step 1: Add 1ml Sodium Bicarbonate Inj. 5% in vial & mix well until clear solution.
Step 2: For I.V use: Add 5ml Sodium Chloride Inj. 0.9% in vial (Step 1) & mix well & use by slow I.V route over 2-3 minutes (Do not put solution in I.V drip).
For I.M use: Add 2ml Sodium Chloride Inj. 0.9% in vial (Step 1) & mix again & use by I.M route.

Gen-M 120mg for Injecton:
Step 1: Add 2ml Sodium Bicarbonate Inj. 5% in vial & mix well until clear solution.
Step 2: For I.V use: Add 10ml Sodium Chloride Inj. 0.9% in vial (Step 1), mix well & use by slow I.V route over 2-3 minutes (Do not put solution in I.V drip).
For I.M use: Add 4ml Sodium Chloride Inj. 0.9% in vial (Step 1), mix again & use by I.M route.

STORAGE:
Store below 30°C.
Protect from heat, light & moisture.

INSTRUCTIONS:
Prepared solution should be used immediately.
Keep all medicines out of the reach of children.

PRESENTATION:
Gen-M 30mg for Injection pack contains:
Single dose vial of artesunate for injection 30mg.
0.5ml ampoule of sodium bicarbonate injection 5%.
2.5ml ampoule of sodium chloride injection 0.9%.

Gen-M 60mg for Injection pack contains:
Single dose vial of artesunate for injection 60mg.
1ml ampoule of sodium bicarbonate injection 5%.
5ml ampoule of sodium chloride injection 0.9%.

Gen-M 120mg for Injection pack contains:
Single dose vial of artesunate for injection 120mg.
2ml ampoule of sodium bicarbonate injection 5%.
10ml ampoule of sodium chloride injection 0.9%.

ہدایات: ڈاکٹر کی ہدایت کے مطابق استعمال کریں۔
۳۰ ڈگری سینٹی گریڈ سے کم درجہ حرارت پر رکھیں، روشنی، گرمی اور نمی سے محفوظ رکھیں۔
تمام دوائیں بچوں کی پہنچ سے دور رکھیں۔

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