ARTESUNATE INJECTION 30 MG
LEVER 30

1.3.1 Summary of Product Characteristic

1. Name of the medicinal product
Artesunate Injection 30mg (LEVER 30)

2. Qualitative and quantitative composition
Each Combipack Contains:

Artesunate Injection 30 mg
Each Vial contains:
Artesunate 30 mg

Sodium Bicarbonate Injection USP
Each Ampoule contains:
Sodium Bicarbonate USP 5% w/v
Water for Injection USP QS

Sodium Chloride Injection USP
Each Ampoule contains:
Sodium Chloride USP 0.9%w/v
Water for Injection USP QS

3. Pharmaceutical form
Powder for injection

4. Clinical particulars
4.1 Therapeutic indications
Treatment of severe falciparum malaria in areas where there is evidence of quinine resistance.

4.2 Posology and method of administration
Severe malaria:
Loading dose: 2.4mg/Kg followed by 1.2mg/Kg at 12 and 24 hours then 1.2mg/Kgdaily for upto 6 days.

Method of Reconstitution
Step 1: Add 0.5 ml 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 & useby 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.

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

4.4 Special warnings and precautions for use
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.

4.5 Interaction with other medicinal products and other forms of interaction
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.

4.6 Pregnancy and lactation
Artesunate should not be used during the first trimester of pregnancy.

4.7 Effects on ability to drive and use machines:
None

4.8 Undesirable 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.

4.9 Overdose
None

5. Pharmacological properties

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: Antimalarial , ATC code: P01BE03

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,causinglysis 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.

5.2 Pharmacokinetic properties

After parenteral administration,artesunate is rapidly hydrolyzed to the active metabolite dihydroartemisinin. OnIntravenous 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.

5.3 Preclinical safety data

None

6. Pharmaceutical particulars

6.1 List of excipients

None

6.2 Incompatibilities

None

6.3 Shelf life

36 Months

Shelf Life after reconstitution: 24 hrs.

6.4 Special precautions for storage

Store in a cool and dry place below 30°C. Protect from Light . Keep out of reach of children.

Srorage Condition after reconstitution: at 2°C-8°C

6.5 Nature and contents of container

Single Dose Vial of Artesunate Injection 30 mg
0.5ml ampoule of Sodium Bicarbonate Injection 5% w/v
2.5ml ampoule of Sodium Chloride Injection 0.9% w/v

6.6 Special precautions for disposal and other handling

No special requirements.

7. Marketed in Nigeria by

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8. Manufactured by

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