80x180 mm Front 80x180 mm Back

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

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Artesunate Injection IP 120 mg

ARTISUN™-120

Composition:
Each vial contains :
Artesunate IP 120 mg
(Sterile Lyophilized Powder)

THERAPEUTIC ACTION
- Artesunate is an antimalarial agents. Artesunate is a derivative of Artemisinin found in Artemisia annua, a herb that has traditionally been used in China for the treatment of malaria.
- Artesunate is an alternative therapy for the treatment of severe malaria, including cerebral Malaria.

INDICATIONS:
Artesunate has an antimalrial activity. It can quickly and reliably control the actute attack and cerebral type of malaria. It is effective against plasmodium falciparum and plasmodium vivax, especially against malaria parasites resistant to Chlorquine.
– Powder for injection, in 60 mg-vial, with one 1 ml-ampoule of 5% sodium bicarbonate and one 5 ml ampoule of 0.9% sodium chloride, for slow IV injection (3 to 5 minutes)or slow IM injection.
– Powder for injection, in 120 mg-vial, with one 2ml-ampoule of 5% sodium bicarbonate and one 10 ml ampoule of 0.9% sodium chloride, for slow IV injection (3 to 5 minutes)or slow IM injection.

ADMINISTRATION:
– Dissolve the powder in the entire volume of 5% sodium bicarbonate and shake the vial until the solution becomes clear. Then, add the 0.9% sodium chloride into the vial:
5 ml of 0.9% sodium chloride to obtain 6 ml of artesunate solution containing 10 mg/ml, for IV injection
2 ml of 0.9% sodium chloride to obtain 3 ml of artesunate solution containing 20 mg/ml, for IM injection

DOSAGE AND DURATION:
– Child under 20 kg: 3 mg/kg/dose
– Child 20 kg and over and adult: 2.4 mg/kg/dose
– One dose on admission (H0) then 12 hours after admission (H12) then 24 hours after admission (H24) then, once daily.
Administer parenterally at least 24 hours (3 doses), then, if the patient can tolerate the oral route, change to a complete 3-day course of an artemisinin-based combination. If not, continue parenteral treatment once daily until the patient can change to oral route (without exceeding 7 days of parenteral treatment).

CONTRA-INDICATIONS, ADVERSE EFFECTS, PRECAUTIONS:
– May cause: gastrointestinal disturbances, dizziness, headache, fever, muscle and joint pain, pruritus; rarely rash, delayed haemolytic anaemia (appearing 2 to 3 weeks after treatment, especially in case of hyperparasitaemia and in young children).
– *Pregnancy: no contra-indication*
– *Breast-feeding: no contra-indication*

Remarks
– The solution should be clear, do not use if the solution is cloudy or if a precipitate is present.
– Do not use water for injection for:
reconstitution (only use sodium bicarbonate);
dilution (only use sodium chloride).

SIDE-EFFECTS:
The most frequent side-effect are mild, transient such as:side-effects on gastrointestinal system (nausea,abdominalpain,diarrhea), headache, dazzling.

PRECAUTIONS:
Use with caution in pregnant women in the first trimester.

NEVER ADMINISTER BY IV INFUSION.

INTERACTIONS:
Due to its structure containing a sesquiterpene lactone that bears a peroxide grouping which releases free oxygen, avoid using Artesunate concomitantly with antioxidants such as VitaminE, VitaminC, Glutathione,.. because those will decrease the antimalarial action of the drug.

SHELF-LIFE:
24 months from the manufacturing date.
Never use after the expiry date clearly indicated on the outer packaging.

OVERDOSAGE :
Experience of acute overdose with artesunate is limited. A case of artesunate overdose has been documented in a 5-year-old child inadvertently administered rectal artesunate at a dose of 88 mg/kg/day (approximately 18 times the maximum recommended daily dose for Artesunate for Injection) for 4 days. Artesunate for Injection is not approved for rectal administration. The overdose was associated with pancytopenia, melena, seizures, multiorgan failure and death. Treatment of overdose should consist of general supportive measures.

STORAGE:
Storage : Store in a cool place, Protect from light.

Keep medicine out of reach of children.

Manufactured by:
Protech Telelinks
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