I.V. / I.M. Injection

Falcijject

فیلسی جیکٹ انجکشن

(آرٹی سونیٹ Ph. Int.) عضلاتی یا وریدی استعمال کیلئے

(Artesunate for Injection Ph. Int.)

COMPOSITION: Each vial contains:
Artesunate Ph. Int. ... 30mg, 60mg or 120mg. [Ph. Int. Specs.]

INDICATIONS: Falcijject Injection is indicated for the initial treatment of severe malaria in adult and pediatric patients. Treatment of severe malaria with **Falcijject Injection** should always be followed by a complete treatment course of an appropriate oral antimalarial regimen.

PHARMACODYNAMICS: Mechanism of action: Artesunate is a hemisuccinate derivative of dihydroartemisinin, which is itself formed by the reduction of Artemisinin. Artemisinin is a sesquiterpene lactone endoperoxide extracted from qinghao (sweet wormwood, Artemisia annua L.), a plant which has been used for centuries in traditional Chinese medicine. Artesunate and the artemisinins are the most rapid acting of the antimalarials, and they have also been shown to enhance splenic clearance of infected erythrocytes by reducing cytoadherence.

PHARMACOKINETICS: Absorption: Intravenous: After intravenous injection Artesunate is very rapidly biotransformed to its active metabolite, dihydroartemisinin (DHA). Consequently, Artesunate half-life (t½) is estimated to be less than 5 minutes. High concentrations of DHA are observed within 5 minutes of Artesunate IV administration.
Intramuscular: Artesunate is rapidly absorbed following intramuscular injection, and peak plasma levels are generally achieved within 30 minutes of administration. The corresponding Artesunate t½ values were estimated to be 48 minutes in children and 41 minutes in adults, and Cmax values were 1.7 and 2.3μmol/L, for children and adults, respectively.
Distribution: Plasma protein binding of dihydroartemisinin was determined to be 93% in patients and 88% in healthy volunteers.
Metabolism: Artesunate is extensively and rapidly hydrolysed by plasma esterases, with possible minimal contribution by CYP2A6. The main metabolite, dihydroartemisinin, accounts for most of the in vivo antimalarial activity of oral Artesunate, however, following IV administration. Artesunate may contribute more significantly.
Elimination: DHA is further metabolized in the liver via glucuronidation and is excreted in the urine; α-dihydroartemisinin-β-glucuronide has been identified as the major urinary product in patients with falciparum malaria.

DOSAGE AND ADMINISTRATION: Adults: Adults and children: Artesunate is administered at a dose of 2.4mg 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.
Preparation: Because of the instability of Artesunate in aqueous solutions the reconstituted solution must be used within one hour of preparation. Therefore the required dose of Artesunate should be calculated and the number of vials of Artesunate needed should be determined prior to reconstituting the Artesunate powder.

RECONSTITUTION METHOD:
Falcijject Injection 30mg: Step 1: Add 0.5ml Sodium Bicarbonate Injection 5% from the ampoule into the vial containing the Artesunate powder. Shake the vial for several minutes to mix well until the powder is completely dissolved and the solution is clear. If the solution appears cloudy or a precipitate is present, it should be discarded.
Step 2: For I.V use: Add 2.5ml Sodium Chloride Injection 0.9% from the ampoule into the vial containing the Artesunate powder & mix well & use by slow I.V route over 2-3 minutes. The reconstituted Artesunate solution should always be used immediately, and discarded if not used within one hour. **Falcijject Injection 30mg** should NOT be administered as an intravenous drip.
For I.M use: Add 1ml Sodium Chloride Injection 0.9% from the ampoule into the vial containing the Artesunate powder& mix again & use by I.M route.
Falcijject Injection 60mg: Step 1: Add 1ml Sodium Bicarbonate Injection 5% from the ampoule into the vial containing the Artesunate powder. Shake the vial for several minutes to mix well until the powder is completely dissolved and the solution is clear. If the solution appears cloudy or a precipitate is present, it should be discarded.
Step 2: For I.V use: Add 5ml Sodium Chloride Injection 0.9% from the ampoule into the vial containing the Artesunate powder& mix well & use by slow I.V route over 2-3 minutes.The reconstituted Artesunate solution should always be used immediately, and discarded if not used within one hour. **Falcijject Injection 60mg** should NOT be administered as an intravenous drip.
For I.M use: Add 2ml Sodium Chloride Injection 0.9% from the ampoule into the vial containing the Artesunate powder & mix again & use by I.M route.
Falcijject Injection 120mg: Step 1: Add 2ml Sodium Bicarbonate Injection 5% from the ampoule into the vial containing the Artesunate powder. Shake the vial for several minutes to mix well until the powder is completely dissolved and the solution is clear. If the solution appears cloudy or a precipitate is present, it should be discarded.
Step 2: For I.V use: Add 10ml Sodium Chloride Injection 0.9% from the ampoule into the vial containing the Artesunate powder& mix well & use by slow I.V route over 2-3 minutes. The reconstituted Artesunate solution should always be used immediately, and discarded if not used within one hour. **Falcijject Injection 120mg** should NOT be administered as an intravenous drip.
For I.M use: Add 4ml Sodium Injection 0.9% from the ampoule into the the vial containing the Artesunate powder & mix again & use by I.M route.
Note: For Intramuscular Injection, withdraw the required volume of Artesunate solution from the vial with a syringe and then inject intramuscularly; the anterior thigh is usually the preferred site for injection. If the total volume of solution to be injected intramuscularly is large, it may be preferable to divide the volume and inject it at several sites, e.g. both thighs.
CONTRAINDICATIONS: Falcijject Injection is contraindicated in patients with hypersensitivity to Artesunate or other Artemisinins.

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OVERDOSAGE: Experience of acute overdose with Artesunate is limited. A case of overdose has been documented in a 5-year-old child who was inadvertently administered rectal Artesunate at a dose of 88mg/kg/day over 4 days, representing a dose more than 7-fold higher than the highest recommended Artesunate dose. The overdose was associated with pancytopenia, melena, seizures, multi-organ failure and death. Treatment of overdose should consist of general supportive measures.

WARNINGS & PRECAUTIONS:
Non-falciparum malaria: Artesunate has not been evaluated in the treatment of severe malaria due to Plasmodium vivax, Plasmodium malariae or Plasmodium ovale.
Resistance to antimalarials: Local information on the prevalence of resistance to antimalarials should be considered in choosing the appropriate combination antimalarial regimen for use with **Falciject Injection.**
Post-treatment haemolytic anaemia: Delayed haemolytic anaemia following treatment with injectable Artesunate has been observed in children in malaria endemic areas and in non-immune travelers presenting with severe falciparum malaria. The risk was most pronounced in patients with hyperparasitaemia and in younger children. Some cases have been severe and required blood transfusion.
Hepatic / renal impairment: Dosage adjustment is not considered necessary in patients with hepatic or renal impairment.
Paediatric population: In clinical trials, the efficacy and safety of intravenous and intramuscular Artesunate have been similar in adult and paediatric populations.

DRUG INTERACTIONS: Artesunate is rapidly and extensively converted to dihydroartemisinin (DHA), the active metabolite, primarily by plasma and erythrocyte esterases. DHA elimination is also rapid (half-life approximately 45 min) and the potential for drug-drug interactions appears limited. In vitro drug-interaction studies have demonstrated minimal effects of Artesunate on cytochrome P450 isoenzymes.

FERTILITY, PREGNANCY AND LACTATION: Pregnancy: Severe malaria is especially hazardous during pregnancy, therefore full dose parenteral Artesunate treatment should be administered at any stage of pregnancy without delay.
Breastfeeding: Limited information indicates that dihydroartemisinin, the active metabolite of Artesunate, is present at low levels in breast milk. The drug levels are not expected to cause any adverse effects in breastfed infants. The amount of drug present in breast milk does not protect the infant from malaria.
Fertility: The relevance of this finding for humans is unknown.
Effects o n ability to drive and use of machines: There is no information on the effect of Artesunate on the ability to drive or use machines. The patient's clinical status should be considered when assessing ability to drive or operate machinery.

ADVERSE REACTIONS: Blood and lymphatic systems disorders:
Uncommon: Neutropenia, anaemia (both occasionally severe) and thrombocytopenia.
Very rare: Pure red cell aplasia.
Frequency unknown: Post-treatment haemolytic anaemia, mild and transient decrease in reticulocyte count.
Nervous system disorders
Common: Dizziness, light-headedness, headache, insomnia and tinnitus (with or without decrease in auditory function).
Very rare: Peripheral neuropathy (or paraesthesia).
Respiratory disorders
Common: Cough and nasal symptoms.
Gastrointestinal disorders
Common: Altered taste, nausea, vomiting, abdominal pain, cramps and diarrhea.
Rare: Raised serum amylase and pancreatitis.
Hepatobiliary disorders
Uncommon: Transient rises in liver transaminases (AST, ALT).
Rare: Hepatitis.
Skin and subcutaneous tissue disorders
Common: Rash and alopecia.
Musculoskeletal and connective tissue disorders
Common: Arthralgia and muscle disorders.
General disorders and administration site conditions
Common: Fatigue, malaise, fever and pain at injection site.
Immune system disorders
Uncommon: Hypersensitivity.

INSTRUCTIONS: Store below 30°C. Protect from heat, light and moisture. Keep out of the reach of children.

PRESENTATION: Falciject Injection 30mg pack contains: Single dose vial of Artesunate for Injection 30mg, one ampoule of 0.5ml Sodium Bicarbonate 5% Injection and 2.5ml ampoule of Celine 0.9% Injection.
Falciject Injection 60mg pack contains: Single dose vial of Artesunate for Injection 60mg, one ampoule of 1ml Sodium Bicarbonate 5% Injection and one ampoule of 5ml Celine 0.9% Injection.
Falciject Injection 120mg pack contains: Single dose vial of Artesunate for Injection 120mg, one ampoule of 2ml Sodium Bicarbonate 5% Injection and 10ml ampoule of Celine 0.9% Injection.

ہدایات: ۳۰° گری سینٹی گریڈ سے کم درجہ حرارت پر رکھیں۔ گرمی، روشنی اور نمی سے بچائیں۔ بچوں کی پہنچ سے دور رکھیں۔

PHARMA

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