**ARTEM**

**ARTEMETHER INJECTION**

**NOMENCLATURE:**
Official Name (Chinese Phonetic): Hojiami Zhusheye
English Name: Artemether Injection
The drug is mainly composed of Artemether. The chemical name is (3*R*, 5*aS*, 6*R*, 8*aS*, 9*R*, 10*S*, 12*R*, 12*aR*)-decahydro-10-methoxy-3, 6, 9-trimethyl-3, 12-epoxy-12*H*-pyrano[4, 3-*j*]-1,2-benzodioxepin.

**PRESENTATION**: Arthemether Injection is available as a colorless or yellowish clear oily solution of artemether in ampoule for intramuscular administration only. Each box contains 6 ampoules.

**FORMULATION:**

**"Adults" presentation:**
**Each ampoule contains: artemether …….80mg**
**Arachis oil …….q.s.f 1ml**
**"Children" presentation:**
**Each ampoule contains: artemether ……. 40mg**
**Arachis oil …….q.s.f 0.5ml**

**PHARMACOLOGY AND TOXICOLOGY:**
Animal pharmacodynamics showed that the drug is a strong schizonticide. Parasitemia clearance occurs rapidly with stable efficacy after administration. It is also effective against chloroquine-resistant *P.falciparum* malaria.
Acute toxicity studies on animals showed that the $LD_{50}$ of Artemether in mice of a single i.g. administration is 895mg/kg and a single i.m. injection is 296 mg/kg; in rats, the $LD_{50}$ of a single i.m. injection is 597mg/kg. This proves the toxicity of Artemether is quite low.

**PHARMACOKINETICS:**
The drug is absorbed rapidly and completely after i.m. injection. The maximum blood concentration of the drug is observed in about 7 hours after i.m. injection of 10mg/kg in human body. The peak value is about 0.8mg/ml with the plasma half-life of about 13 hours. It is widely distributed in the body with the highest level found in the brain and followed by liver and kidney. It is mainly excreted in the feces with a part in urine.

**INDICATIONS:**
Antimalarial drug. For the treatment of severe malaria including the chloroquine-resistant *P.falciparum* malaria.

**USAGE AND DOSAGE**
The drug is used for intramuscular injection, five days course with the initial dose of 3.2mg/kg, followed by 1.6mg/kg for the following 4 days.
The initial dose for adults is 160mg (2 ampoules), followed by 80mg (1 ampoule) every time from the $2^{nd}$ to $5^{th}$ day. The dose for children or overweight patients should be decreased or increased on the basis of the individual weight or under the doctor's prescription.

**ADVERSE REACTIONS:**
Clinical dosage exhibits slight adverse reactions. A transient low fever and reticulocytopenia may occur in individual cases. Slight rise of SGOT may occur in individual cases. Arrhythmia may occur in rare cases (such as ventricular tachycardia).

**CONTRAINDICATIONS:**
Preclinical studies have consistently shown that artemisinin and its derivates do not exhibits mutagenic or teratogenic activity, but all of these drugs caused fetal resorption in rodents at relatively low doses of 1/200-1/400 of the $LD_{50}$, i.e > 10mg/kg, when given after the sixth day of gestation. Reports on the use of these drugs during pregnancy are limited. How ever malaria can be particularly hazardous during pregnancy. Artemisinin and its derivates are therefore the drugs of choice for severe malaria and can be used for the treatment of uncomplicated malaria during the second and third trisemester of pregnancy in areas of inadequacy of current knowledge on the use of these drugs during pregnancy should be understood by prescribers and all such use should, principle, be monitored. Clinical outcomes of both succesful and adverse nature should be reported to regulatory authorities.

**PRECAUTIONS:**
1. Do not exceed the recommended dose.
2. Due to electrocardiographic QT prolongation reported in some patients treated with artemether, it is recommended to avoid the concomitant prescription of medications known to produce a prolongation of the QT internal or to monitor patients receiving such demication: erythromycin, terfenadine, astemizole, probucol, class 1a anti-arrhythmic agents (quinidine, procainamide, disopyramide), class III anti-arrhythmic (amiodarone, bretylium), bepridil, sotalol, tricyclic anti-depressant, certain neuroleptics and phenothiazines.
3. For the emergency treatment of patients suffering from severe malaria, the intramuscular injection is referred.

**PREGNANCY AND LACTATION**
Owing to lack of date, uses in the first trimester of pregnancy is not recommended.

**DRUGS INTERACTIONS:**
Studies and reviews in the literature demonstrated that the active substance of Artemether had no interactions with other drugs on decreasing therapeutic effects and increasing toxic and side effects in bodies.

**OVERDOSE:**
Although no case of overdosage has been documented, in case of accident, symptomatic treatment is recommended under the instruction of doctors.

**VALIDITY:**
Four years.

**STORAGE CONDITION:**
Preserve in well-closed container, protected from light under $20^0C$.

**PACKAGE:**
Adults Package: 1ml x 6 ampoules per paper box.
Children Package: 0.5ml x 6 ampoules per paper box.

Harus dengan resep dokter.

Importer: PT. Multi Mitra Biotech
Menara Gracia 2nd Floor, Jl. HR.Rasuna Said, Kav. C-17,
Jakarta 12940 Indonesia

**MANUFACTURER:**

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