ARTESIANE ®

ß-artemether
300 mg KIT

SEVERE MALARIA

Single-dose, injectable treatment

POWERFUL, FAST AND RADICAL

Ready-to-use kit

DAFRA PHARMA INTERNATIONAL

Headquarters
Slachthuisstraat 30/7
2300 Turnhout
Belgium

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Setting the Standard

www.dafrapharma.com

ARTESIANE®

ß-artemether
300 mg KIT

EUROPEAN GMP

SEVERE MALARIA

Single-dose, injectable treatment

POWERFUL, FAST AND RADICAL

Sterile syringe

+

Cleansing swab

+

READY-TO-USE KIT

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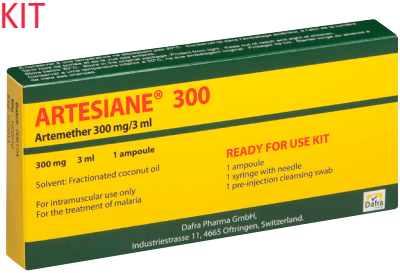

PRESENTATION

Ready-to-use kit containing an injectablesolution of artemether at a dose of 300 mg + a syringe and a sterile alcohol swab.

THERAPEUTIC INDICATIONS

ARTESIANE® injectable IM is recommendedfor the treatment of malaria caused by all forms of plasmodium, including drug-resistant strains.

DOSAGE AND INSTRUCTIONS FOR USE

The dosage depends on the severity of the case and the patient's clinical status. Intramuscular injections of artemether are generally used in severe cases such as cerebral malaria and also in patients with gastrointestinal problems.

Initial dose

For adults weighing 50 kg or more, one 300-mg vial administered IM per day for 1 to 3 days.

Maintenance dose

A switch to oral medication is made with an artemisinine-based combination therapy for a period of 3 days (for example,CO-ARINATE FDC®).

PRECAUTIONS FOR USE

Do not exceed the dose prescribed without medical advice.

PREGNANCY AND BREASTFEEDING

The use of medications during the period of organogenesis (the first three months) is not advised unless the physician feels that the benefits outweigh the risks, such as in the case of cerebral malaria, for example. No evidence of embryotoxicity or teratogenicity has been reported in humans.

Breastfeeding: The passage of artemether into breast milk is not known.

DRUG INTERACTIONS

No specific interactions have been observed. However, potentialization of other antimalarial agents is common. An initial dose of artemether followed by other antimalarial agents demonstrates a clear potentialization, bringing about a rapid cure.

UNDESIRABLE EFFECTS

At the therapeutic dose (see dosage), no adverse effect is usually observed with artemether. However, in some rare cases, minor changes on laboratory tests may occur: reduction in the number of reticulocytes and minor, transient increase in transaminases. In general, these abnormalities do not result in noticeable clinical manifestations.

Sometimes a slight decrease in heart rate (transient anomaly) may be noted. Anomalies on an electrocardiogram have not been demonstrated. Abdominal cramps and mild diarrhoea have been reported at high doses.

PHARMACOLOGICAL PROPERTIES

Pharmacodynamics

Artemether essentially acts as a blood schizonticide. The presence of the peroxide bond (releasing an atom of oxygen and free radicals, very cytotoxic for the plasmodia) is critical in its antimalarial activity. The inhibition of protein synthesis as the primary mechanism of action is suggested by certain studies which demonstrate morphological changes in the ribosomes and endoplasmic reticulum. Morphological alterations of the plasmodic membranes triggered by artemether have beendescribed in several studies. These modifications may result in activity of the free radicals, combined with oxidation phenomena which occur after dissociation of the peroxide function.

Pharmacokinetics

Artemether administered intramuscularly is rapidly absorbed in the blood and reaches therapeutic levels after 30 to 60 minutes.The product is then metabolized in the liver and dihydroartemisinine forms which itself is also active as an anti-malarial agent. The elimination half-life of the product is about5 to 8 hours. Protein binding varies according to the species studied. In humans, it is 50%.

STORAGE

Store below 30°C, in the original package, protected from light. Keep out of reach and sight of children.

Shelf life: Under these conditions, the ampoules have a shelf life of 3 years. Do not use after the expiry date, stated on the packaging. The expiry date refers to the last day of that month.

For the complete SMPC, please visit www.dafrapharma.com