			
20 mg / ml 10 ampoules paediatric form	40 mg / ml 10 ampoules paediatric form	80 mg / ml 5 ampoules	100 mg / ml 10 ampoules

ARTESIANE® INDICATION

Treatment of severe malaria caused by all species of Plasmodium parasites (including the most resistant strains).

ARTESIANE® POSOLOGY - JUNIORS

Weight	Days of treatment	Number of ampoules and mg	Total dose
5 - 6 kg	1st day	1 ampoule 20 mg	3 ampoules 20 mg
	2nd - 5th day	½ ampoule 20 mg	
7 - 14 kg	1st day	1 ampoule 40 mg	1 ampoule 40 mg + 4 ampoules 20 mg
	2nd - 5th day	1 ampoule 20 mg	
15 - 24 kg	1st day	1 ampoule 80 mg	1 ampoule 80 mg + 4 ampoules 40 mg
	2nd - 5th day	1 ampoule 40 mg	
25 - 34 kg	1st day	1 ampoule 80 mg	1 ampoule 80 mg + 4 ampoules 40 mg
	2nd - 5th day	1 ampoule 40 mg	

ARTESIANE® POSOLOGY - ADULTS

Weight	Days of treatment	Number of ampoules and mg	Total dose
35 - 50 kg	1st day	2 ampoule 80 mg	6 ampoules 80 mg
	2nd - 5th day	1 ampoule 80 mg	
51 - 74 kg	1st day	2 ampoule 100 mg	6 ampoules 100 mg
	2nd - 5th day	1 ampoule 100 mg	
75 - 100 kg	1st day	3 ampoules 100 mg or 3 ampoules 80 mg	11 ampoules 100 mg or 11 ampoules 80 mg
	2nd - 5th day	2 ampoules 100 mg or 2 ampoules 80 mg	

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ARTESIANE®

ß - artemeter
20 – 40 – 80 – 100 mg

EUROPEAN G M P

PREFERRED FOR TREATMENT OF SEVERE MALARIA IN CHILDREN AND ADULTS

Intramuscular treatment of malaria Plasmodium in all its forms:

- Severe malaria
  - Brain
  - Hematuria
  - Malaria with anemia and hypoglycemia
  - G6PD deficiency
  - Patients with gastrointestinal problems
- Uncomplicated malaria

TREATMENT FOR MALARIA IN ALL ITS FORMS

Dafra PHARMA

Setting the standard

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ARTESIANE ®

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20 – 40 – 80 – 100 mg

PRESENTATION

ARTESIANE® 20 mg: Infants - Children
Box of 10 injectable ampoules containing 20 mg of artemether.
ARTESIANE® 40 mg: Adolescents
Box of 10 injectable ampoules containing 40 mg of artemether.
ARTESIANE® 80 mg: Adults < 70 kg
Box of 5 injectable ampoules containing 80 mg of artemether.
ARTESIANE® 100 mg: Adults > 70 kg
Box of 10 injectable ampoules containing 100 mg of artemether.

INDICATIONS

ARTESIANE® 20 and 40 mg is indicated in the treatment of malaria in children caused by all forms of plasmodium, including chemo-resistant strains.

ARTESIANE® 80 and 100 mg is recommended in the treatment of malaria in adults caused by all forms of plasmodium, including chemo-resistant strains.

POSOLOGY AND METHOD OF ADMINISTRATION

The dosage depends on the severity of the case and the clinical state of the patient. Formulations for intramuscular injection of Artemether are mostly used in case of severe malaria, such as cerebral malaria, but also in case of patients showing gastrointestinal problems.

Loading dose for children and adults:
3.2 mg/kg body weight administered as a single intramuscular injection on the first day. For practical purposes, administrating a full ampoule to patients with a body weight of more than 50 kg, is not harmfull and has a longer effect.

Maintenance dose for children and adults:
1.6 mg/kg/day administered as intramuscular injection once a day during the following four days.

Maintenance treatment can also be continued by oral Artemisinin-based combination therapy (ACT), if the patient's condition does not require injections.
The drug is given by intramuscular injection in the gluteal muscle or the quadriceps.
Combination of other drugs in the same syringe should not be done. Aseptic conditions must be respected when injecting Artemether.

Note:
A full course therapy of five days is essential in order to avoid recrudescence. In case of severe malaria it may be necessary to increase the loading dose and to prolong treatment for seven days if parasitaemia is not cleared during the first few days.

PRECAUTIONS FOR USE

Pregnancy: The use of medications during the period of organogenesis is not recommended unless the physician believes that the benefits outweigh the risks, in the case of cerebral malaria, for example. No proof of embryotoxicity has been reported in humans.

Breastfeeding: It is not known whether artemisinin (artesunate, artemether) derivatives pass into breast milk.
Dosage: Do not exceed the prescribed dose without medical advice.

DRUG INTERACTIONS
No specific drug interaction has been reported.

UNDESIRABLE EFFECTS
At the therapeutic dose, no undesirable effect is usually observed. However, in a few cases, slight biological changes may occur: reduction in the number of reticulocytes and slight increase in transaminases. In general, these disruptions do not give rise to clinically perceptible manifestations.
A slight decrease in heart rate has been noted on a few occasions, a temporary abnormality. At high doses, abdominal cramps and mild diarrhoea have been reported.

PHARMACOLOGICAL PROPERTIES
Artemisinin and its semisynthetic derivatives like artesunate and artemether are schizonticides for all forms of plasmodium. Its semisynthetic derivatives are provided with a peroxide bridge that opens to the interior of the parasite by forming native oxygen as well as free radicals. This primary mechanism of action makes artemether effective and fast acting.

PHARMACOKINETICS
ARTESIANE® 20, 40, 80 and 100 mg administered intramuscularly is absorbed rapidly in the blood and reaches therapeutic levels after 30 to 60 minutes. The elimination half-life of the product is around 1 to 2 hours. Protein binding varies according to the species studied. In humans it is around 50%.

CONSERVATION
Store below 30°C, in the original package, protected from light and humidity. Keep out of reach and sight of children. Do not use after the expiry date, stated on the packaging (Exp.). The expiry date refers to the last day of that month.

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