CO-ARTESIANE ®

artemether & lumefantrine

THE REFERENCE SUSPENSION FOR CHILDREN

IN THE ANTI-MALARIAL MARKET

COMBINATION THERAPY THAT UNITES TOLERANCE AND EFFICACY

Be healthy,
Live longer!

DAFRA PHARMA INTERNATIONAL

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Setting the Standard

www.dafrapharma.com

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EUROPEAN GMP

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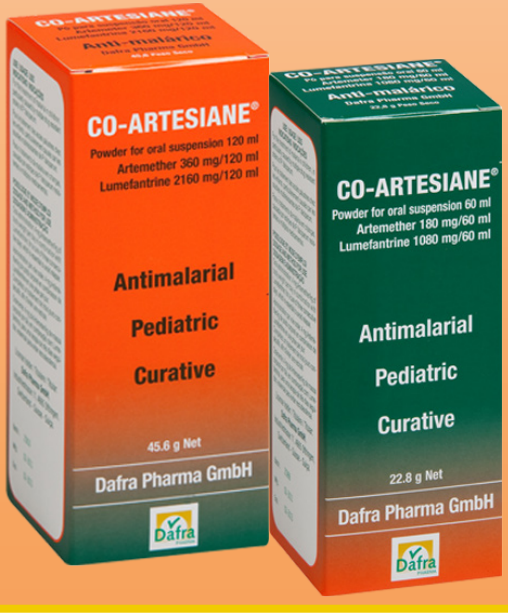

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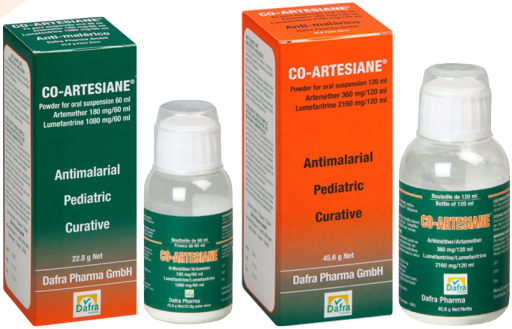

PRESENTATION

Bottle of 60 ml containing 180 mg artemether and 1080 mg lumefantrine. Bottle of 120 ml containing 360 mg artemether and 2160 mg lumefantrine.

INDICATION

CO-ARTESIANE® is recommended in children for curative treatment of malaria caused by any form of plasmodium including drug-resistant strains of Plasmodium falciparum.

POSOLOGY AND METHOD OF ADMINISTRATION

The recommended daily dose is 4 mg / kg body weight of artemether and 24 mg / kg body weight of lumefantrine once a day (ratio 1/6). Duration of the treatment: 3 consecutive days. After opening the bottle, fill with good quality water till 60 ml or 120 ml mark.
The mixture turns yellow and has the pleasant taste of coconut. Shake the bottle vigorously so that the powder is dissolved. 1 teaspoon equals to 5 ml.

WEIGHT	FROM 1ST TO 3RD DAY
3 to 4 kg	1 teaspoon –5 ml
5 to 7 kg	2 teaspoons –10 ml
8 to 11 kg	3 teaspoons –15 ml
12 to 15 kg	4 teaspoons –20 ml
16 to 18 kg	5 teaspoons –25 ml
19 to 22 kg	6 teaspoons –30 ml
23 to 26 kg	7 teaspoons –35 ml
27 to 30 kg	8 teaspoons –40 ml

CONTRAINDICATIONS

There are no strict contraindications for using artemether in children suffering from malaria.

DRUG INTERACTIONS

No specific interaction has been reported with the use of artemether. Artemether may potentiate the effects of other antimalarial drugs.

CO-ARTESIANE® should not be co-administered with halofantrine and quinine.

SIDE EFFECTS

At therapeutic doses, **CO-ARTESIANE®** is usually well tolerated. During clinical studies, a few benign biological alterations were reported: decreased reticulocyte count and slight increase in transaminase levels. Normally, these perturbations do not lead to perceptible clinical manifestations.

PHARMACOLOGICALPROPERTIES

Pharmacodynamics

The components of CO-ARTESIANE® exert specific actions on all forms of plasmodium including the drug-resistant strains. Artemether contains a peroxide bridge which opens up inside the parasite and releases nascent oxygen which induces the formation of free radicals. Lacerations of the membrane structure were interpreted as the mechanism of action. These direct cytotoxic effects on the cells would be the essence of the mechanism of action of artemether and the reason for its quick action and efficacy in severe malaria. Artemether is a schizonticide and gametocide on all forms Plasmodium. Lumefantrine mostly intervenes in the polymerization process. The inhibition of protein synthesis has been suggested as the mechanism of action of the two components in studies showing morphological abnormalities morphological in ribosomes and endoplasmic reticulum.

PHARMACOKINETICS

Artemether administered orally is rapidly absorbed and reaches maximum plasma levels after 60-90minutes. The product is metabolized in the liver and is converted to dihydroartemisinin (DHA) which itself also acts as an active antimalarial agent. The half- life of elimination of DHA is about 2 to 4 hours. Protein binding varies between the species studied and in humans, it is about 50%.

PHARMACEUTICAL PARTICULARS

Shelf life: 2 years.

Special precautions for storage: Store below 30°C, in the original package, protected from light. Keep out of reach and sight of children. In a closed bottle **CO-ARTESIANE®** powder is stable. After reconstitution, the suspension should be used within a period of maximum 4 weeks. Longer conservation is not recommended.

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