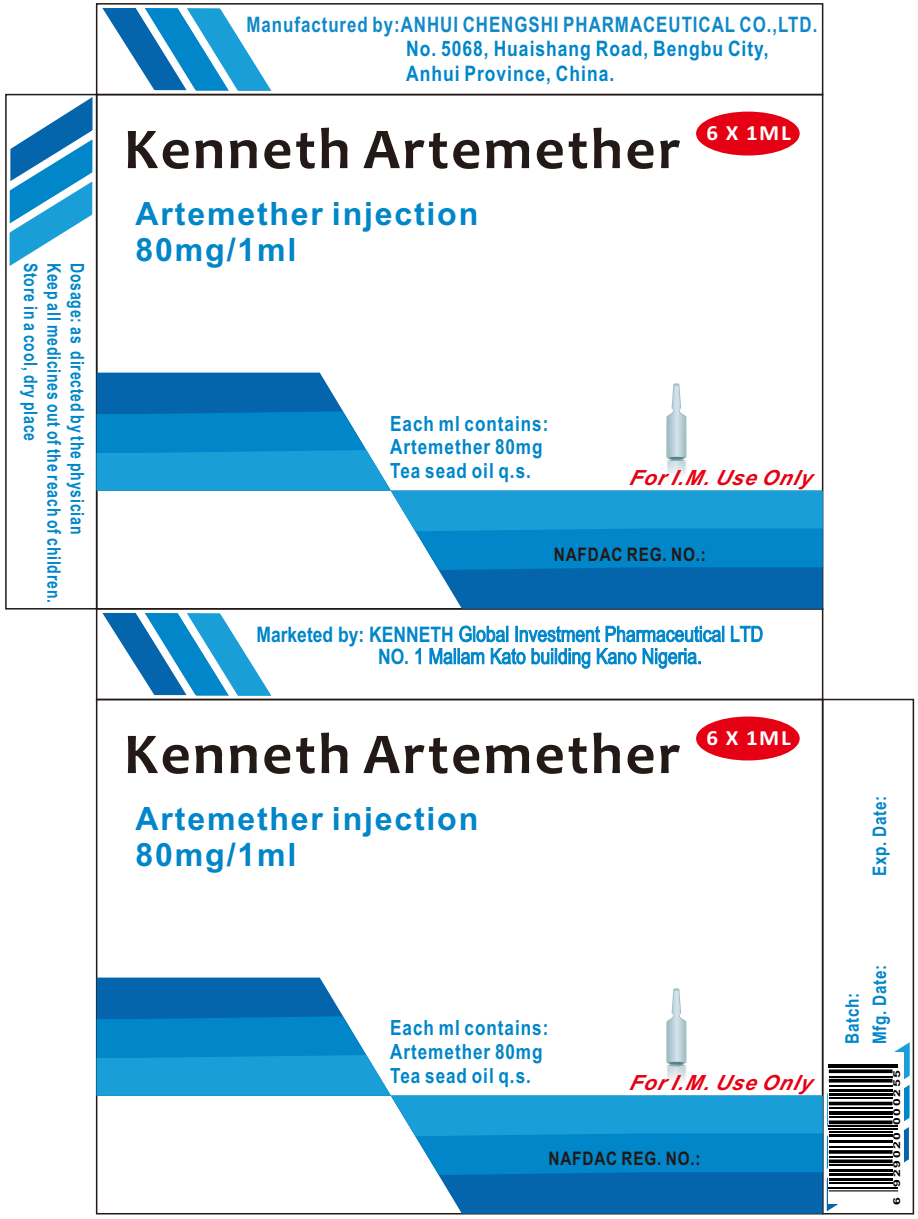
Manufactured by:ANHUI CHENGSHI PHARMACEUTICAL CO.,LTD.
No. 5068, Huaishang Road, Bengbu City,
Anhui Province, China.
Kenneth Artemether
6 X 1ML
Artemether injection
80mg/1ml
Dosage: as directed by the physician
Keep all medicines out of the reach of children.
Store in a cool, dry place
Each ml contains:
Artemether 80mg
Tea sead oil q.s.
For I.M. Use Only
NAFDAC REG. NO.:
Marketed by: KENNETH Global Investment Pharmaceutical LTD
NO. 1 Mallam Kato building Kano Nigeria.
Kenneth Artemether
6 X 1ML
Artemether injection
80mg/1ml
Each ml contains:
Artemether 80mg
Tea sead oil q.s.
For I.M. Use Only
NAFDAC REG. NO.:
Exp. Date:
Batch:
Mfg. Date:

Kenneth Artemether

Artemether injection 80mg/1ml

SMPC

PRODUCT INFORMATION

1. Name of the medicinal product

1.1 Name of the medicinal product

Artemether Injection

1.2 Strength

80 mg/1 ml

1.3 Pharmaceutical form

Injection

2. Qualitative and quantitative composition

Each 1 ml ampoule contains artemether 80 mg.

3. Pharmaceutical form

Injection.

Colorless

4. Clinical particulars

4.1 Therapeutic indications

Artemether Injection is indicated for treatment of acute, uncomplicated malaria infections due to Plasmodium falciparum in patients of 5 kg bodyweight and above. Artemether Injection has been shown to be effective in geographical regions where resistance to chloroquine has been reported.

4.2 Posology and method of administration

The drug is for intramuscular injection, for a period of 5 days and not exceeding a total of 480mg for adults.

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.

	Day-1	Day-2	Day-3	Day-4	Day-5
Adults	160 mg (2 ampoules)	80 mg (1 ampoule)	80 mg (1 ampoule)	80 mg (1 ampoule)	80 mg (1 ampoule)
Children	4mg/kg bodyweight	2mg/kg bodyweight	2mg/kg bodyweight	2mg/kg bodyweight	2mg/kg bodyweight

4.3 Contraindications

Hypersensitivity.

Pregnancy, unless the doctor considers it essential as in the case of cerebral malaria.

4.4 Special warnings and precautions for use

Artemether should be used for the treatment of severe falciparum malaria only where there is evidence that the antimalarial efficacy of quinine is declining.

For children, since the injected volumes will be small, it is advisable to use a 1-ml syringe to ensure that the correct dose is given.

In cerebral malaria and complicated malaria, general supporting therapy may be required.

4.5 Interaction with other medicinal products and other forms of interaction

Artemether causes QT prolongation in some patients. Thus, concomitant use of erythromycin, terfenadine, procainamide, quinidine, disopyramide, amiodarone, bretylium, bepridil, sotalol, astemizole, probucol, tricyclic antidepressants, phenothiazines may be avoided.

4.6 Pregnancy and lactation

Animal reproduction studies have shown an adverse effect on the fetus and there are no adequate and well-controlled studies in humans, but potential benefits may warrant use of the drug in pregnant women despite potential risks.

4.7 Effects on ability to drive and use machines

Not available.

4.8 Undesirable effects

Artemether has been remarkably well-tolerated, and appears less toxic than quinine or chloroquine; adverse effects include bradycardia, electrocardiogram abnormalities, gastrointestinal disturbances, dizziness, injection site pain, skin reactions, and fever. Transient decreases in neutrophils and reticulocytes have been reported in some patients treated with artemether.

Drug induced fever has been observed with artemether. Mild reactions were seen in patients to whom artemether had been administered intramuscularly. These included nausea, hypotension, dizziness and tinnitus.

These side effects were also reported: dark urine, sweating, somnolence, and jaundice. There were no deaths or any other side effects. No irreversible side effects were seen.

Slight rise of SGOT and SGPT may occur in individual cases. Neurological side effects have not yet been observed in clinical use but clinical trials suggest that coma may be prolonged in patients treated with artemether and there was an increased incidence of convulsions in one trial in cerebral malaria. Transient first degree heart block has been documented in three patients receiving artemether.

Neurotoxicity has been observed in animal studies but not in humans.

Cardiotoxicity has been observed following administration of high doses of Artemether.

4.9 Overdose

There is no experience with overdose with artemether. There is no specific antidote known for the artemisinin derivatives.

However, experimental toxicological results obtained with large doses of artemisinin on the cardiovascular system and the CNS should be considered. Overdosage could bring on cardiac irregularities. An ECG should be taken before initiating treatment in cardiac patients. Irregularities in the pulse should be looked for and cardiac monitoring carried out if necessary. The animal results on the CNS suggest that overdose could result in changes in brain stem function. Clinicians treating cases of overdosage should look for changes in gait, loss of balance, or changes in ocular movements and reflexes.

5. Pharmacological properties

5.1 Pharmacodynamic properties

In the body, artemether is metabolized into the active metabolite metabolite dihydroartemisinin. The drug works against the erythrocytic stages of P. falciparum by inhibiting nucleic acid and protein synthesis. Artemether is administered in combination with lumefantrine for improved efficacy. Artemether has a rapid onset of action and is rapidly cleared from the body. It is thought that

artemether provides rapid symptomatic relief by reducing the number of malarial parasites.

Lumefantrine has a much longer half life and is believed to clear residual parasites.

5.2 Pharmacokinetic properties

Absorption of artemether is improved 2- to 3-fold with food. It is highly bound to protein (95.4%). Peak concentrations of artemether are seen 2 hours after administration.

Artemether is metabolized in the human body to the active metabolite, dihydroartemisinin, primarily by hepatic enzymes CYP3A4/5. Both the parent drug and active metabolite are eliminated with a half-life of about 2 hours.

Mechanism of Action

Artemether is an artemisinin derivative and the mechanism of action for artemisinins is unknown. One of the proposed mechanisms is that through inhibiting anti-oxidant and metabolic enzymes, artemistinin derivatives inflict oxidative and metabolic stress on the cell. Some pathways affected may concern glutathione and glucose metabolism. As a consequence, lesions and reduced growth of the parasite may result.

Another possible mechanism of action suggests that arteristinin drugs exert their cidal action through inhibiting PfATP6. Since PfATP6 is an enzyme regulating cellular calcium concentration, its malfunctioning will lead to intracellular calcium accumulation, which in turns causes cell death.

Metabolism

Rapidly hydrolysed to the active metabolite dihydroartemisinin.

Excretion

Elimination half-life: about 4-11 hr after IM.

5.3 Preclinical safety data

Toxicity

Animal studies on acute toxicity show that the LD50 of Artemether in mice is a single i.g. administration of 895mg/kg and a single i.m. injection of 296mg/kg dose; in rats, the LD50 is a single i.m. injection of 597mg/kg dose.

Carcinogenicity

Carcinogenicity studies with the artemether were not conducted.

6. Pharmaceutical particulars

6.1 List of excipients

Tea Tree Oil

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

3 years

6.4 Special precautions for storage

Store in a room temperature below 30^0c

6.5 Nature and contents of container

Type I clear glass ampoule containing 1 ml solution for injection.

Package of 6 ampoules per box.

6.6 Special precautions for disposal

Not applicable.

7. MANUFACTURED BY:

ANHUI CHENGSHI PHARMACEUTICAL CO.LTD

No. 5068, Huaishang Road, Bengbu City, Anhui Province, China.

8. MARKETED BY:

KENNETH GLOBAL INVESTMENT PHARMACEUTICAL LTD.

NO. 1 Mallam Kato building Kano Nigeria.