



Anhui Chengshi Pharmaceutical Co.,Ltd
安徽城市药业股份有限公司

SUMMARY OF PRODUCT CHARACTERISTICS (SmPC)

1-Name of the Medicinal Product : Artemether Injection 80mg/1ml

1.1 Product Name: Artemether Injection

1.2 Strength: 80mg/1ml

1.3 Pharmaceutical Dosage Form: solution for injection

2-Quality and Quantitative Composition :

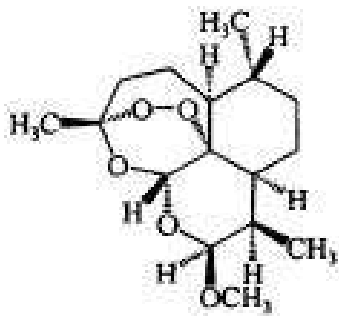
2.1 Qualitative Declaration

The active substance of the Artemether Injection is Artemether.

Artemether: White crystals or crystalline powder, odorless, taste slightly bitter, Very soluble in chloroform or acetone, freely soluble in ethanol or ethyl acetate, practically insoluble in water.

The molecular formula of Artemether: $C_{16}H_{26}O_5$

The structural formula of Artemether :



The molecular weight of Artemether : 298.4

The CAS number of Artemether : 71963-77-4

2.2 Quantitative Declaration

Artemether Injection 80mg/1ml

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Dosage form: small volume injection

Concentration: 80mg/1ml

Product description: 1ml of Colorless to light yellow transparent oily liquid is filled in the glass ampoule (1ml) .

Ingredients	Quantity per ampoule (1ml)	Function of ingredients
Artemether	80mg	Active substance
Benzyl alcohol	20 mg	Disinfectant
Refined Soya Oil	1ml	Solvent

3-Pharmaceutical Form :

Dosage form: small volume injection

1ml of Colorless to light yellow transparent oily liquid is filled in the glass ampoule (1ml) .

4-Clinical Particulars

4.1 Therapeutic indications

Applicable to all types of malaria, but mainly used for the treatment of chloroquine falciparum malaria and dangerous falciparum malaria emergency.

4.2 Posology and method of administration

1. Normal dosage for adults, intramuscular injection, the first dose 160mg (2 doses), once a day from the 2nd day, 80mg (1 dose) each time, for 5 days.
2. Normal dosage for children, intramuscular injection, the first dose according to body weight 3.2mg/kg; From the 2nd day to the 5th day, 1.6mg/kg per body weight, once a day.

4.3 Contraindications

It's not clear.

4.4 Special warning and precautions for use

If the product is cold and solidifies, it can be used after mild temperature dissolution.

4.5 Interaction with other medicinal products and other forms of Interactions

This experiment has not been conducted and there are no reliable references

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4.6 Pregnancy and lactation

Use with caution in pregnant women.

4.7 Child medication

This experiment has not been conducted and there are no reliable references

4.8 Elderly medication

This experiment has not been conducted and there are no reliable references

4.9 Undesirable effects

The adverse reactions of this product are mild, some patients have mild elevation of aspartate aminotransferase and alanine aminotransferase, and reticulocyte may have transient reduction.

4.10 Overdose

This experiment has not been conducted and there are no reliable references

4.11 Pharmacology and toxicology

1. Pharmacology:

Artemether, a derivative of artemisinin, has a powerful and rapid killing effect on the red stage of plasmodium, and can quickly control the clinical onset and symptoms. The mechanism of action of artemisinin is not clear. It mainly interferes with the membrane - mitochondrial function of plasmodium parasites. Artemisinin changed the membrane structure of plasmodium falciparum by affecting the ultrastructure of the endored stage. Due to the action of the food vesicle, the nutrient uptake of the plasmodium is blocked, and the plasmodium loses a large amount of cytoplasm and nutrients, but can not be replenishment, so it quickly dies. The mechanism of action is the production of unstable organic free radicals and/or other electron-philic mediators via the decomposition of hemoglobin via its internal peroxide (dioxygen) bridge, which then forms covalent admixture with plasmodium proteins and causes plasmodium death. Artemether is six times more active against malaria than artemisinin.

2. Toxicology:

The median lethal dose (LD₅₀) of artemether was 895-977mg /kg for oral administration in mice and 597mg/kg for intramuscular injection of artemether oil in rats. Subacute toxicity test showed that there were no other adverse reactions except decreased reticulocyte after intramuscular administration of artemether oil 18mg/kg for 14 days. This drug has certain embryonic toxicity, manifested as embryonic absorption.

4.4 Pharmacokinetics

Rapid and complete absorption after intramuscular injection. After intramuscular injection of 10mg/kg, the peak time of blood drug reached 7 hours, the peak reached

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about 0.8mg/L, and the half-life ($t_{1/2}$) was about 13 hours. It is widely distributed in the body, mostly in brain tissue, followed by liver and kidney. Excretion is mainly through the intestine, followed by urine excretion.

5-Pharmaceutical Particulars

5.1 Shelf life
36months

5.2 Special precautions for storage
Shading and airtight storage.stored below 30 °C.

6-Marketing Authorization Holder :

Anhui Chengshi Phamaceutical Co., Ltd.
No. 5068 Huaishang road,Bengbu,Anhui province, China

7-Name Of Manufacturer :

Anhui Chengshi Phamaceutical Co., Ltd.
No. 5068 Huaishang road,Bengbu,Anhui province, China

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		1ml x 6 Ampoules	
		MEDITEX	
		ARTEMETHER INJECTION 80mg/1ml	
		Composition: Each 1ml contains Artemether 80mg	
		Manufactured by: Anhui Chengshi Pharmaceutical Co., Ltd No. 5068 Huaishang Road, Bengbu, Anhui province, China Distributed in Nigeria by: JUSTEEN PHARMACEUTICALS LTD. 57B, Coker Road, Ilupeju, Lagos, Nigeria	
		NAFDAC Reg.No.: A4-3891 Batch No.:240205 Mfg. Date: 02/2024 Exp. Date: 02/2027	
ARTEMETHER INJECTION	1ml x 6 Ampoules		
	MEDITEX		
	ARTEMETHER INJECTION 80mg/1ml		
	Composition: Each 1ml contains Artemether 80mg		
		STORE IN A COOL, DARK AND DRY PLACE BELOW 25°C DIRECTION FOR USE, SEE ENCLOSED LEAFLET KEEP AWAY FROM THE REACH OF CHILDREN	

MY100 C70Y55

蒿甲醚小盒240205
成品尺寸: 90x64x12mm
SXMJ-2023.12.13



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<div>Manufactured by: Anhui Chengshi Pharmaceutical Co., Ltd No. 5068 Huashang Road, Bengbu/Anhui province, China Distributed in Nigeria by: JUSTEEN PHARMACEUTICALS LTD. 57B, Coker Road, Ilupeju, Lagos, Nigeria</div>			
<div>Composition: Each 1ml contains Artemether 80mg</div>			
<div>ARTEMETHER INJECTION 80mg/1ml</div>			
<div>MEDITEX</div>			
<div>10 x 1 x 6 Ampoules</div>			
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MY100 C70Y55

蒿甲醚中盒240205
成品尺寸: 126x95x66mm
SXMJ-2023.12.13



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ARTEMETHER INJECTION 80mg/1ml

COMPOSITION 80mg/1ml:

Each 1 ml contains:
Artemether 80 mg
Oily Base q.s.

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.

Take this medication exactly as it is described in this leaflet or as your doctor or pharmacist has told you.

- Keep this leaflet. You may need to read it again.

If you need clarification or advice, consult your pharmacist.

- If you have any side effects, talk to your doctor or pharmacist if you notice any side effects not listed in this leaflet.

If you do not feel better or worse after 3 days of treatment, you must see a doctor.

THERAPEUTIC INDICATIONS

Anti-malarial: Artemeter is indicated for the treatment of malaria, caused by all forms of Plasmodium including severe malaria caused by strains resistant to multiple drugs of P. falciparum.

DOSAGE AND ADMINISTRATION

INTRAMUSCULAR INJECTION ONLY.

Recommended dosage

The dosage depends on the severity of the case and the clinical condition of the patient. Artemeter intramuscular injection formulations are primarily used in cases of severe malaria, such as cerebral malaria, but also in the case of patients with gastrointestinal problems.

Loading dose for adults and children: 3.2 mg / kg body weight given as a single intramuscular injection on the first day.

Maintenance dose for adults and children: 1.6 mg / kg / day administered as an intramuscular injection once daily for the next four days.

Maintenance therapy may also be continued by combined oral artemisinin (ACT) therapy if the patient's condition does not require injections.

The medicine is given by intramuscular injection into the gluteus muscle or quadriceps.

The combination of other drugs in the same syringe should be avoided. Aseptic conditions must be respected when injecting Artemeter.

A full five-day therapy is essential to prevent further growth.

In case of severe malaria, it may be necessary to increase the loading dose and prolong the treatment for seven days if the parasitemia is not eliminated during the first days.

CONTRAINDICATIONS

Pregnancy, unless the doctor considers it essential.

Contraindications should be stated so that the dosage form is recorded, as they may differ for other forms of the same drugs. These should be presented as they may appear on, say, the label of the preparation. Special precautions to be taken with respect to administration in the presence of certain medicinal products, other predisposing conditions or sensitivity to any of the ingredients, should be presented. Special warning and precaution for use

The resistance of Plasmodium to Artemeter was not observed. It is unlikely that resistance will occur due to the specific mechanism of action of Artemeter, which is very cytotoxic to Plasmodia (opening of a peroxide bridge). An apparent resistance is seen at times, but it is mainly due to multiple litters of Plasmodia developing at different times in the same patient.

In controlled studies, the resurgence does not exceed 3%. In case of recrudescence (actual or apparent), a new complete treatment of 5 days is recommended.

Interaction with other medicinal products and other forms of interaction

Specific drug interactions were not observed. Artemeter potentiates the antimalarial activity of other antimalarials.

Pregnancy and breast-feeding

The safe use of β -artemether in pregnant women and during breastfeeding has not yet been fully established.

Although drug use is not recommended during pregnancy (and particularly not during the first semester), malaria can have a devastating effect on the mother and fetus and there is a significant risk of a fatal negative outcome. Other antimalarials are not harmless and it is of paramount importance to reduce parasitaemia as soon as possible.

This can easily be achieved by intramuscular injection of artemether. Numerous pregnant women of various races and ethnicities have been treated with artemether during the past few years and there have been no reported undesirable effects for either the mother or fetus or for babies.

Lactation: It is not known whether artemether is excreted in breast milk.

It is recommended that β -artemether be administered only to pregnant women if the expected benefits outweigh the potential risks.

Effects on ability to drive and use machines:

None known

UNDESIRABLE EFFECTS

At the therapeutic dose there are virtually no side effects. There are reports of laboratory abnormalities, ie, decreased reticulocyte counts, increased transaminase and ECG changes (bradycardia and first-degree AV block). However, these are transient.

At high doses, transient abdominal pain, diarrhea, and tinnitus may occur.

Such effects may be due to the medication itself, to the patient's predisposition condition, to an interaction with other substances present in the body or to other factors. These may be insignificant, but their monitoring is necessary. Describe the observed effect, the likelihood that they will be due to the drug, or other predisposing or interposing factors, such as concomitant therapy.

The severity and course of side effects should be noted, as well as the prescribed action to be taken for each observed effect.

Overdose and special antidotes

Do not exceed the prescribed dose. A specific antidote is not known. The administration of several times the therapeutic dose has not been reported as causing serious adverse events. In case of accidental and severe overdose symptomatic treatment is recommended in a specialized center.

HOW TO STORE ARTEMETER INJECTION

Store in a dry place, below 30°C, protect from light.

Keep medicines out of reach of children.

Do not use this medicine after the expiry date which is stated on the label and carton.

The expiry date refers to the last day of that month. Keep ampoules in the outer carton in order to protect from light. Medicinal products intended for parenteral administration should be visually inspected prior to administration to detect any particulate matter and discoloration. Do not use if the solution is darker than light yellow or otherwise discolored.

PRESENTATION

6 Ampoules in one inner carton, such 10 inners packed in outer carton.

Manufactured by:

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Distributed in Nigeria by:

JUSTEEN PHARMACEUTICALS LTD.
57B, Coker Road, Ilupeju, Lagos, Nigeria

城市-蒿甲醚小盒240205说明书 尺寸: 115x130mm



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ARTEMETHER INJ
80MG/1ML I.M.
BATCH NO.:240205
MFG: 02/2024
EXP: 02/2027
Anhui Chengshi Pharma



Anhui Chengshi Pharmaceutical Co.,Ltd
安徽城市药业股份有限公司

用230905改



C:74 Y:60 K:10



M:100 Y:100



K:10

蒿甲醚240205(27.5*21*35.5cm)

MEDITEX

injection

Artemether Injection
80mg/1ml
for I.M. use Only

6 Amps x 10Boxes x 20

Manufactured by :

ANHUI CHENGSHI PHARMACEUTICAL CO.,LTD
No. 5068, Huaishang Road, Bengbu
Anhui Province, China

Distributed in Nigeria by:

Justeen Pharmaceuticals Ltd.
57b, Coker Rd. Ilupeju, Lagos,



NAFDAC Reg. NO.:A4-3891

BATCH NO.: 240205

MFG. DATE: 02/2024

EXP. DATE: 02/2027

MEASURE: 27.5 x 21 x35.5CM

G.W.: 5.8 KGS

HANDLE WITH CARE!