

## **SUMMARY OF PRODUCT CHARACTERISTICS**

- 1. NAME OF THE MEDICINAL PRODUCT**  
Ciromether-40 / Artemether Injection 40 mg/ml
- 2. QUALITATIVE AND QUANTITATIVE COMPOSITION**  
Each ml contains:  
Arthemether 40mg
- 3. PHARMACEUTICAL FORM**  
Solution for Injection  
A clear, colourless oily solution
- 4. CLINICAL PARTICULARS**
  - 4.1 Therapeutic indications**  
Treatment of severe and complicated malaria caused by P.falciparum both in adults and children in areas where there is multidrug resistance. Treatment of uncomplicated malaria in situations where there is widespread prevalence of multidrug resistant P. falciparum infection
  - 4.2 Posology and method of administration**  
The drug is used for intramuscular injection.  
  
Adults: Five days course with the initial dose of 3.2mg/kg on day one, followed by 1.6mg/kg for the next 4 days. The initial dose for adults is 160mg (2 ampoules each containing 80mg artemether), followed by 80mg (1 ampoule containing 80mg artemether) each time from the 2nd to the 5th day. The dose for overweight patients should be increased on the basis of the individual weight or under the doctor's prescription.  
Children: Five days course with the initial dose of 3.2 mg/kg on day one, followed by 1.6 mg/kg for the next 4 days..
  - 4.3 Contraindications**  
Hypersensitivity to artemether or other artemisinin compounds. Artemether is not recommended in the first trimester of pregnancy because of limited data.
  - 4.4 Special warnings and precautions for use**  
The ampoules should be stored at room temperature in their original containers and protected from light. Under these conditions the injectable forms have a shelf life of 3 years.
  - 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, Bepidil, Sotalol, Pstemizole, Probuco, Tricyclic Antidepressants, Phenothiazines may be avoided.
  - 4.6 Fertility, pregnancy and lactation**  
It should be used with caution in the first trimester of pregnancy since some fetus absorption has been observed.
  - 4.7 Effects on ability to drive and use machines**  
Not relevant.

#### **4.8 Undesirable effects**

Clinical dosage exhibits slight adverse reactions. A transient low fever and reticulocytopenia may occur in individual cases. Slight rise of SGOT and SGPT may occur in individual cases. Arrhythmia may occur in rare cases (such as ventricular tachycardia).

#### **4.9 Overdose**

Although no case of overdose has been documented, in case of accident, symptomatic treatment is recommended under the instruction of doctors.

### **5. PHARMACOLOGICAL PROPERTIES**

#### **5.1 Pharmacodynamic properties**

Pharmacotherapeutic group: Antimalarials, blood schizonticide ATC code: P01BE02

Animal pharmacodynamics showed that the drug is a strong schizonticide. Parasitemia Clearance occurs rapidly with stable efficacy after administration. It is also effective against chloroquine-resistant *P. falciparum* malaria.

#### **5.2 Pharmacokinetic properties**

The drug is absorbed rapidly and completely after IM injection. The maximum blood concentration of the drug is observed in about 7 hours after i.m. injection of 10mg/kg in human body. The peak value is about 0.8g/ml with the plasma half-life of about 13 hours. It is widely distributed in the body with the highest level found in the brain and followed by liver and kidney.

It is mainly excreted in the feces with a part in urine.

#### **5.3 Preclinical safety data**

There is no preclinical data available that is of relevance to the prescriber.

### **6. PHARMACEUTICAL PARTICULARS**

#### **6.1 List of excipients**

Benzyl alcohol, butylated hydroxyanisole, Fractionated coconut oil

#### **6.2 Incompatibilities**

Not known

#### **6.3 Shelf life**

36 Months

#### **6.4 Special precautions for storage**

Store below 30°C. Protect from light.

#### **6.5 Nature and contents of container and special equipment for use, administration or implantation**

6 x 2ml USP type-I flint ampoule packed in carton with a leaflet.

#### **6.6 Special precautions for disposal <and other handling>**

None.

**7. MARKETING AUTHORISATION HOLDER**

Ciron Drugs & Pharmaceuticals Pvt. Ltd.  
C- 1101 /1102, Lotus Corporate Park, Graham Firth Steel Compound,  
Jay Coach Junction, Western Express Highway, Goregaon (East)  
Mumbai- 400 063, India.

**8. MARKETING AUTHORISATION NUMBER(S)**

07672/08467/REN/2022

**9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION**

Date of first authorisation: 16/11/2018

Date of latest renewal : 08/08/2022

**10. DATE OF REVISION OF THE TEXT**

14/07/2023

**11. Reference**

<https://www.dafrapharma.com/wp-content/uploads/2021/06/smpc-artesiane-inject.pdf>