SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE MEDICINAL PRODUCT

Lumether-80/ Artemether Injection 80 mg/ml

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml contains:
Arthemether 80mg

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

Adults: First day: 80 mg administered by IM route twice a day at a 12 hourly interval (=160 mg/day). Following 4 days: 80 mg administered by IM route once a day. The dose should not be exceed 480 mg in adults.
Children: First day: 1.6 mg/kg of body weight administered by IM route twice a day at a 12 hourly (= 3.2 mg /Kg body wt/day). Following 4 days: 1.6 mg/Kg of body weight administered by IM route once a day. The dose should not be exceed 9.6 mg/ kg in children.

Posology and mode of administration: Intramuscular Only

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, Bepridil, Sotalol, Pstemizole, Probucol, 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 1ml 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)

07934/08472/REN/2022

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 19.09.2019
Date of latest renewal : 09.10.2022

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