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CIN NO: U24231GJ1992PLC018237

SUMMARY OF PRODUCT CHARACTERISTICS (SmPC)

1. Name of the medicinal product

1.1. Name of the medicinal product:

Generic Name/INN Name: Artemether & Lumefantrine Tablets

Trade Name: ARTEMEF-80/480 TABLETS

1.2 Strength:

Artemether .....80 mg

Lumefantrine ..... 480 mg

1.3 Pharmaceutical form: Solid Oral Dosage form (Tablet)

2. Qualitative and Quantitative composition:

Sr. No.	Ingredients	Specification	Qty. per Tablet (in mg)	% w/w	Function
Mixing & Binding (Part -I)					
1.	Artemether	In-House	80.000	11.834	Active
2.	Ethyl Cellulose	BP	1.595	0.236	Binder
3.	Isopropyl Alcohol	BP	15.000	----	Solvent
Mixing & Binding (Part -II)					
4.	Lumefantrine	In-House	480.000	71.006	Active
5.	Maize Starch	BP	34.405	5.089	Diluent
6.	PVP K-30	BP	6.00	0.888	Binder
7.	Isopropyl Alcohol	BP	115.435	-----	Solvent
Lubrication					
8.	Colloidal Silicon dioxide	BP	4.000	0.592	Glidant
9.	Magnesium Stearate	BP	9.000	1.331	Lubricant
10.	Sodium starch glycolate	BP	20.000	2.959	Disintegrant
11.	Purified Talc	BP	15.000	2.219	Lubricant
Total weight of uncoated Tablet			650.00 mg		
film coating					
12.	Isopropyl Alcohol	BP	217.390	----	Solvent
13.	Dichloromethane	BP	326.080	----	Solvent
14.	Di-Ethyl Phthalate	BP	3.260	0.482	Film- forming agent
15.	Polyethylene Glycol 6000	USP-NF	1.305	0.193	Plasticizer
16.	H.P.M.C. E-15	BP	10.045	1.487	Film- forming agent

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17.	Purified Talc	BP	7.045	1.042	Anti-tacking agent
18.	Titanium Dioxide	BP	2.175	0.322	Opacifier
19.	Col. Tartrazine Lake	In-House	2.17	0.321	Coloring agent
Net weight of film coated Tablet: 676.00 mg				100.00	

3. Pharmaceutical form:

Dosage Form: Tablets (Oral solid dosage form)

Visual & Physical characteristics of the product: A yellow coloured capsule shape, biconvex, film coated tablets having a embossed A/L on one side & 80/480 on other side & breakline on both side of tablets.

4. Clinical particulars

4.1. Therapeutic indications:

Artemef-80/480 Tablet is indicated for the treatment of acute uncomplicated Plasmodium falciparum malaria in adult, children and infants of 5 kg and above.

Consideration should be given to official guidance regarding the appropriate use of anti-malarial agents.

4.2. Posology and method of administration:

Posology:

Tablets for oral administration.

To increase absorption, Artemef-80/480 Tablets should be taken with food or a milky drink. If patients are unable to tolerate food, Artemef-80/480 Tablets should be administered, but the systemic exposure may be reduced. Patients who vomit within 1 hour of taking the medication should repeat the dose.

For administration to small children and infants, the tablet/s may be crushed.

Adults and children weighing 35 kg and above

For patients 12 years of age and above and 35 kg body weight and above, a course of treatment comprises six doses of four tablets i.e. total of 24 tablets, given over a period of 60 hours as follows: the first dose of four tablets, given at the time of initial diagnosis, should be followed by five further doses of four tablets given at 8, 24, 36, 48 and 60 hours thereafter.

Children and infants weighing 5 kg to less than 35 kg

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A six-dose regimen is recommended with 1 to 3 tablets per dose, depending on bodyweight:
5 to less than 15 kg bodyweight: the first dose of one tablet, given at the time of initial diagnosis, should be followed by five further doses of one tablet given at 8, 24, 36, 48 and 60 hours thereafter.
15 to less than 25 kg bodyweight: the first dose of two tablets, given at the time of initial diagnosis, should be followed by five further doses of two tablets given at 8, 24, 36, 48 and 60 hours thereafter.
25 to less than 35 kg bodyweight: the first dose of three tablets, given at the time of initial diagnosis, should be followed by five further doses of three tablets given at 8, 24, 36, 48 and 60 hours thereafter.

Method of administration

Oral administration

4.3. Contraindications:

Artemef-80/480 Tablets are contraindicated in:

- Patients with known hypersensitivity to the active substances or to any of the excipients.
- Patients with severe malaria*.
- Patients who are taking any drug which is metabolized by the cytochrome enzyme CYP2D6 (e.g. metoprolol, imipramine, amitryptyline, clomipramine).
- Patients with a family history of sudden death or of congenital prolongation of the QTc interval on electrocardiograms, or with any other clinical condition known to prolong the QTc interval.
- Patients taking drugs that are known to prolong the QTc interval (proarrythmic). These drugs include:

- Antiarrhythmics of classes IA and III,
- Neuroleptics, antidepressive agents,
- Certain antibiotics including some agents of the following classes: macrolides, fluoroquinolones, imidazole and triazole antifungal agents,
- Certain non-sedating antihistamines (terfenadine, astemizole),
- Cisapride.
- Flecainide

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• Patients with a history of symptomatic cardiac arrythmias or with clinically relevant bradycardia or with congestive cardiac failure accompanied by reduced left ventricle ejection fraction.

• Patients with disturbances of electrolyte balance e.g. hypokalemia or hypomagnesemia.

• Patients taking drugs that are strong inducers of CYP3A4 such as rifampin, carbamazepine, phenytoin, St. John's wort (Hypericum perforatum).

Clinical manifestation: Prostration; impaired consciousness or unarousable coma; failure to feed; deep breathing, respiratory distress (acidotic breathing); multiple convulsions; circulatory collapse or shock; pulmonary edema (radiological); abnormal bleeding; clinical jaundice; hemoglobinuria

4.4. Special warnings and precautions for use:

Artemef-80/480 Tablets must not be used in the first trimester of pregnancy in situations where other suitable and effective antimalarial are available.

Artemether and Lumefantrine have not been evaluated for the treatment of severe malaria, including cases of cerebral malaria or other severe manifestations such as pulmonary oedema or renal failure.

Due to limited data on safety and efficacy, Artemef-80/480 Tablets should not be given concurrently with any other antimalarial agent unless there is no other treatment option.

If a patient deteriorates whilst taking Artemether and Lumefantrine, alternative treatment for malaria should be started without delay. In such cases, monitoring of the ECG is recommended and steps should be taken to correct any electrolyte disturbances.

The long elimination half-life of lumefantrine must be taken into account when administering quinine in patients previously treated with Artemether and Lumefantrine.

If quinine is given after Artemether and Lumefantrine, close monitoring of the ECG is advised.

If Artemef-80/480 Tablets is given after mefloquine, close monitoring of food intake is advised.

In patients previously treated with halofantrine, Artemef-80/480 Tablets should not be administered earlier than one month after the last halofantrine dose.

Artemef-80/480 Tablets is not indicated and has not been evaluated for prophylaxis.

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