SUMMARY OF PRODUCTS CHARACTERISTICS

1. NAME OF THE MEDICINAL PRODUCT:

Artemether and Lumefantrine Dispersible Tablets (20 mg / 120 mg)
(LUFEMAX JUNIOR DISPERSIBLE)

2. QUALITATIVE AND QUANTITATIVE COMPOSITION:

Each uncoated dispersible tablet contains:
Artemether Ph. Int. 20 mg
Lumefantrine Ph. Int. 120 mg
Excipients Q.S.
Color: Lake of Quinoline Yellow.

Notable Effect: Aspartame

3. PHARMACEUTICAL FORM

Uncoated Dispersible Tablets

4. CLINICAL PARTICULARS

4.1 Therapeutic Indication

LUFEMAX JUNIOR tablets are indicated for the treatment of P.falciparum malaria cases resistant to both Chloroquine and Sulphadoxine-pyrimethamine combination.

4.2 Posology and Method of Administration

LUFEMAX JUNIOR should be taken with food or drinks rich in fat such as milk as the absorption of both Artemether and Lumefantrine is increased. Grapefruit juice should be used cautiously during LUFEMAX JUNIOR treatment. In the event of vomiting within 1 hour of administration, repeat dose should be taken. A standard 3 days treatment schedule with a total of 6 doses is recommended.

Body Weight	**Artemether + Lumefantrine**					
	Day 1		**Day 2**		**Day 3**	
5 kg to 15 kg	**Morning**	**Evening**	**Morning**	**Evening**	**Morning**	**Evening**
	20 + 120	20 + 120	20 + 120	20 + 120	20 + 120	20 + 120

Instruction for Administration:

The dispersible tablet(s) composing 1 dose should be completely dispersed in a small amount of water. Stir gently and administer immediately to the patient. Rinse the glass with an additional small amount of water and give immediately to the patient.

4.3 Contraindications

LUFEMAX JUNIOR is contraindicated in:

- Patients with known hypersensitivity to the active substances or to any of the excipients.
- Patients who are taking any drug which is metabolised 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, 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).

4.4 Special warnings and precautions for use

LUFEMAX JUNIOR has 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, LUFEMAX JUNIOR should not be given concurrently with any other antimalarial agent unless there is no other treatment option. Use with caution in patients with severe hepatic or renal insufficiency and patients refusing food intake. If quinine is given after LUFEMAX JUNIOR, close monitoring of the ECG is advised. If LUFEMAX JUNIOR is given after mefloquine, close monitoring of food intake is advised. In patients previously treated with Halofantrine LUFEMAX JUNIOR should not be administered earlier than one month after the last Halofantrine dose. LUFEMAX JUNIOR is not indicated and has not been evaluated for prophylaxis. Caution is recommended when combining LUFEMAX JUNIOR with drugs exhibiting variable patterns of inhibition, moderate induction or competition for CYP3A4 as the therapeutic effects of some drugs could be altered. Drugs that have a mixed inhibitory/induction effect on CYP3A4, especially anti-retroviral drugs such as HIV protease inhibitors and non-nucleoside reverse transcriptase inhibitors should be used with caution in patients taking LUFEMAX JUNIOR. Caution is recommended when combining LUFEMAX JUNIOR with hormonal contraceptives.

Aspartame is source of Phenylalanine. This medicine should be used with caution in patients with Phenylketonuria. Neither non-clinical data are available to assess aspartame use in infants below 12 weeks of age.

4.5 Interaction with other medicinal products and other forms of Interaction

LUFEMAX JUNIOR is having interaction with drugs that are known to prolong the QTc interval, with drugs metabolized by CYP2D6, with strong inducers of CYP3A4 such as Rifampin, with other antimalarial drugs, with CYP3A4 inhibitors, with weak to moderate inducers of CYP3A4, with anti-retroviral drugs such as protease inhibitors

and non-nucleoside reverse transcriptase inhibitors, with drugs metabolized by CYP450 enzymes, with hormonal contraceptives.
This medicine must not be taken in combination with the following medicines: Ketoconazole. Itraconazole, Miconazole or Voriconazole, Cimetidine, clarithromycin or erythromycin, Ritonavir, Nelfinavir, Lopinavir, Indinavir, Amitriptyline, Clomipramine, Imipramine, Flecainide, Metoprolol, Mexiletine, Propafenone, Procainamide, Disopyramide, Amiodarone, quinidine, sotalol, chlorpromazine, Thioridazine, haloperidol, Astemizole or Terfenadine, Cisapride, Moxifloxacin, Pentamidine.

4.6 Pregnancy and lactation

Pregnancy: LUFEMAX JUNIOR must not be used in the first trimester of pregnancy in situations where other suitable and effective antimalarials are available.
Lactation: Women taking LUFEMAX JUNIOR should not breast-feed during their treatment. Due to the long elimination half-life of Lumefantrine (2 to 6 days), it is recommended that breast-feeding should not resume until at least one week after the last dose of LUFEMAX JUNIOR unless potential benefits to the mother and child outweigh the risks of LUFEMAX JUNIOR treatment.

4.7 Effects on ability to drive and use machines

Not known.

4.8 Undesirable effects

Headache, Dizziness, loss of appetite, Disturbances of the gut such as nausea, vomiting, diarrhoea or abdominal pain, Fatigue, Weakness or loss of strength (asthenia). Cough, Pain in the muscles and joints. Rash or itching, Awareness of your heartbeat (palpitations), Abnormal heart rhythm.

4.9 Overdose

In cases of suspected overdosage symptomatic and supportive therapy should be given as appropriate, which should include ECG and blood potassium monitoring.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Artemether and Lumefantrine, have their own action site in the malarial parasite. The presence of the endoperoxide bridge in Artemether, generating singlet oxygen and free radicals which are very cytotoxic to the plasmodia, appears to be essential for antimalarial activity. Morphological changes of the parasitic membranes induced by Artemether have been described as being the result of free-radical action. Lumefantrine interferes more in the polymerization processes. Both Artemether and Lumefantrine have a secondary action involving inhibition of nucleic acid and protein synthesis within the malarial parasite.

5.2 Pharmacokinetic properties

Orally administered Artemether is rapidly absorbed reaching therapeutic levels within 60-90 minutes. Artemether is metabolized in the liver to the demethylated derivative dihydroartemisinin (DHA). The elimination is rapid, with a $T_{1/2}$ of 2-4 hours. The binding of Artemether with plasma protein in man is about 50%. Radioactivity distribution of Artemether was found to be equal between cells and plasma. The absorption of Lumefantrine is highly influenced by lipids and food intake (from 10% by fasten to 100% at normal diet). Lumefantrine is N-debutylated in human liver microsomes. This metabolite has 5 to 8 fold higher antiparasitic effects than Lumefantrine. Lumefantrine is found to be highly protein bound (95%). The elimination half-life in malaria-attaint patients will be 4 to 6 days. Lumefantrine and its metabolites are found in bile and faeces.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipient(s)

Microcrystalline Cellolose (200), Sodium Lauryl Sulfate, Crospovidone, Polacrilin Potassium (Kyron T 314), Croscarmellose Sodium, Colloidal Anhydrous Silica, Aspartame, Flavour Trusil Mango Special, Flavour Trusil Peppermint Special, Lake of Quinoline Yellow, Magnesium Stearate.

6.2 Shelf-life

24 months

6.3 Special precautions for storage

Store below 30°C. Protect from light and moisture.
Store in the original package.

6.4 Nature and contents of container

6 Tablets are Alu-Alu Blister packed. Such 1 Alu-Alu Blister is packed in a Printed Baby Carton with packing insert. Such 10 Baby Cartons are packed in a printed Mother Carton.

7. MARKETING AUTHORISATION HOLDER

BIOMATRIX HEALTHCARE PVT LTD.
Survey No. 624, Sarkhej – Bavla Highway, Vil.: Rajoda,
Tal.: Bavla, Dist.: Ahmedabad – 382220, Gujarat, INDIA.

8. MARKETING AUTHORISATIONNUMBER

09337/10393/NMR/2022

9. Date of authorization

Dec 23, 2023