GEN-M®

(Artemether/Lumefantrine)
Tablets Ph.Int.

20mg/120mg, 40mg/240mg, 80mg/480mg Tablets Ph. Int.
Dispersible Dispersible

Powder for Oral Suspension Ph. Int.
DS Powder for Oral Suspension Ph. Int.

جین ایم

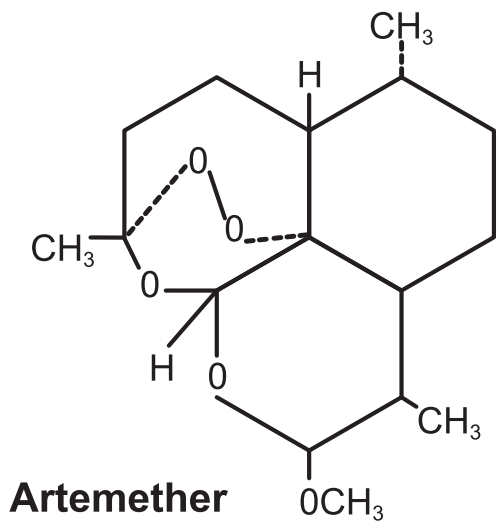
(آرٹیمیتھر/لومیفینٹرن)

۲۰ ملی گرام/۱۲۰ ملی گرام ڈسپرسبل ٹیبلٹس انٹرنیشنل فارماکوپیا
۴۰ ملی گرام/۲۴۰ ملی گرام ڈسپرسبل ٹیبلٹس انٹرنیشنل فارماکوپیا
۸۰ ملی گرام/۴۸۰ ملی گرام ٹیبلیٹس انٹرنیشنل فارماکوپیا

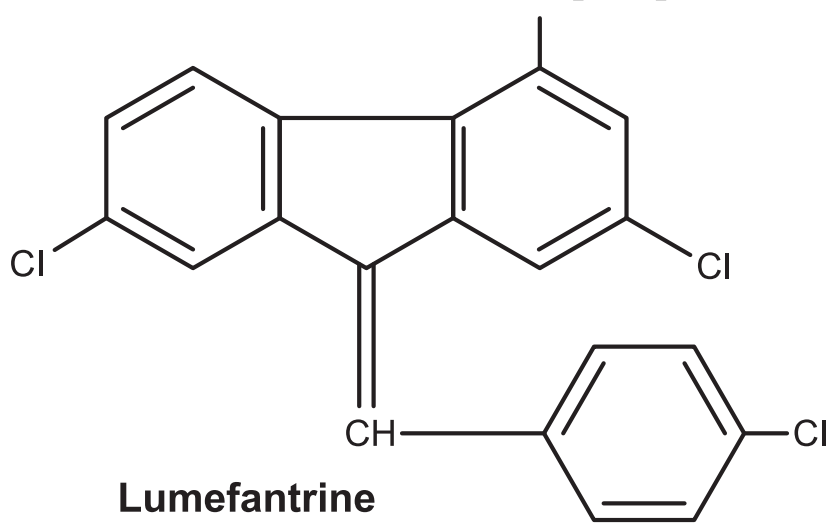
اورل سسپنشن انٹرنیشنل فارماکوپیا
ڈی ایس اورل سسپنشن انٹرنیشنل فارماکوپیا

Description: Gen-M is a new treatment of malaria. It is the fixed combination of Artemether (Methyl-ether derivative of Artemisinin) & Lumefantrine (fluorene derivative belonging to aminoalcohol class).

Chemical Structure:



Artemether



Lumefantrine

QUALITATIVE AND QUANTITATIVE COMPOSITION:

Gen-M Dispersible Tablets 20mg/120mg Ph. Int.
Each dispersible tablet contains:
Artemether Ph.Int. 20mg
Lumefantrine Ph.Int..120mg

Gen-M Dispersible Tablets 40mg/240mg Ph. Int.
Each dispersible tablet contains:
Artemether Ph.Int. 40mg
Lumefantrine Ph.Int..240mg

Gen-M Tablets 80mg/480mg Ph. Int.
Each tablet contains:
Artemether Ph.Int.....80mg
Lumefantrine Ph.Int..480mg

GEN-M Powder for Oral Suspension Ph. Int.
After Reconstitution:
Each 5ml contains
Artemether Ph.Int. 15mg
Lumefantrine Ph.Int. 90mg

GEN-M DS Powder for Oral Suspension Ph. Int.
After Reconstitution:
Each 5ml contains
Artemether Ph.Int. 30mg
Lumefantrine Ph.Int. 180mg

Properties: Artemether is the most active derivate of the Artemisinin, a new class of antimalarial drugs derived from Artemisinin. The latter compound is extracted from the plant Artemisia Annua, Artemether is prepared semi-synthetically & Lumefantrine is a synthetic aryl amino alcohol.

PHARMACOLOGICAL PROPERTIES:

Pharmacodynamics: Both components Artemether/ Lumefantrine have their own action site in the malarial parasite. The presence of the endoperoxide bridge in Artemether (generating single oxygen and free radicals, those 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, being the result of free-radical action, Lumefantrine interferes more in the polymerization processes, other in vitro test suggest that both cause a marked diminution of nucleic acid synthesis Inhibition of protein synthesis as the basic mechanism of action is suggested in studies which showed morphological changes in ribosomes as well as in the endoplasmic reticulum. Although Artemether acts essentially as a blood

schizonticide. Artemether/Lumefantrine did clear gametocytes in comparative clinical trials.

Pharmacokinetics: Orally administered Artemether is rapidly absorbed reaching therapeutic levels within 60-90 minutes. Artemether is metabolized in the liver to the demethylated derivate dihydroartemisinin (DHA). The elimination is rapid, with a T½ of 2-4 hours. Dihydroartemisinin, being a potent antimalarial itself has a T½ of about 2-4 hours. The degree of binding to plasma proteins varied markedly according to the species studied. 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), therefore parents should be encouraged to give the medication with some fatty food as soon as it can be tolerated. 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 bounded (95%). The elimination half life in malaria, patients will be 4 to 6 days. Lumefantrine and its metabolities are found in bile and faeces.

Therapeutic Indication: Gen-M (Artemether / Lumefantrine) is indicated for the treatment of uncomplicated *P. falciparum* malaria including multi-drug resistant strains of *P. falciparum*. **Gen-M** is also effective against the blood stage of *P. vivax* but not active against hypnozoites. **Gen-M** (Artemether / Lumefantrine) must be used for the malaria infections acquired in areas where the parasites may be resistant to other anti-malarial drugs.

"World Health Organization recommends Artemether / Lumefantrine as a first line treatment for the acute uncomplicated *P. falciparum* malaria for both multi-drug resistant areas & drug sensitive areas".

Dosage & Administration:

Patients with acute malaria are frequently averse to food. The dose may be encouraged to resume normal eating as soon as food can be tolerated since this improves absorption of artemether and lumefantrine. In the event of vomiting within 1 hour of administration a repeat dose should be taken.

6-dose regimen should be given for 3 days as oral treatment 1st dose at the time of initial diagnosis & than at 8, 24, 36, 48, 60hrs.

For Tablets:

GEN-M

Dosage according to Body Weight

20mg/120mg Tablets Dispersible

5 to 14kg	1 b.i.d for 3-days

40mg/240mg Tablets Dispersible

15 to 24kg	1 b.i.d for 3-days
25 to 34kg	1½ b.i.d for 3-days

80mg/480mg Tablets

Adults & over 35kg	1 b.i.d for 3-days

Take medicine as per doctor's directions. دوا کی خوراک ڈاکٹر کی ہدایت کے مطابق لیں۔

Take the tablet after meal with boiled water or milk (preferably milk). کھانا کھانے کے بعد دوا پانی یا دودھ کیساتھ لیں۔ (دوا دودھ کیساتھ لینا بہتر ہے)

Dispersible tablet should be used after dissolving in plain water. ڈسپرسبل ٹیبلٹ کو سادہ پانی میں حل کر کے پئیں۔

Take complete course of medicine otherwise infection may return. دوا کا کورس پورا کریں ورنہ بیماری دوبارہ ہوسکتی ہے

Gen-M Oral Suspension 30ml & 60ml:

Body Weight	Dose	Duration
5kgs	7ml	Once Daily for 3-days
7.5kgs	10ml	
10kgs	14ml	
15kgs	20ml	

Gen-M DS Oral Suspension:

Body Weight	Dose	Duration
5kgs	3.5ml	Once Daily for 3-days
7.5kgs	5ml	
10kgs	7ml	
15kgs	10ml	

Contraindication:

Gen-M (Artemether / Lumefantrine) is contraindicated to those patients which have a history of hypersensitivity to Artemether / Lumefantrine.

PRECAUTION:

Pregnancy: There are no adequate data from the use of Artemether / Lumefantrine in pregnant women. **Gen-M** (Artemether / Lumefantrine) treatment should only be considered if the expected benefit to the mother outweighs the risk to the fetus.

Lactation: Gen-M (Artemether / Lumefantrine) excretes into breast milk. It should not be taken by breast-feeding women.

Drug Interaction:

Patients who are taking any drug which inhibits the cytochrome enzyme CYP3A4 (e.g. erythromycin, ketoconazole, itraconazole, cimetidine, HIV protease inhibitors, etc.)

Patients who are taking any drug which is metabolized by the cytochrome enzyme CYP2D6 (e.g. flecainide, metoprolol, imipramine, amitryptyline, clomipramine, etc.)

Unwanted Side Effects:

Artemether/Lumefantrine is well tolerated and there is no drug induced serious unwanted side effects. The most common adverse experiences (>1%) in patients treated with Artemether/Lumefantrine combination are abdominal pain, diarrhoea, vomiting, nausea, palpitation, headache, dizziness & arthralgia.

The preclinical investigations and the clinical trial programs revealed no cardiotoxicity with Artemether/Lumefantrine combination and to date there have been no reports of adverse clinical cardiac events. Recent studies comparing Artemether/Lumefantrine with Halofantrine in humans showed a clear distinction between the two substances and confirmed no sign of cardiotoxicity with Artemether/Lumefantrine combination.

Pharmaceutical Precautions:

Artemether/Lumefantrine bottles should be stored at room temprature. In a closed bottle Artemether/Lumefantrine granules are stable.

After reconstitution suspension is stable for a minimum of 14-days. Longer conservation is not recommended.

Direction for reconstitution:

To make 30ml/60ml suspension or DS suspension add some water invert bottle and shake well until all granules are dispersed.

Then slowly add more water up to the mark on the bottle. Use only cool, boiled water.

PRESENTATION OF SUSPENSION:

Gen-M Oral Suspension

Gen-M Powder for Oral Suspension is available in **30**ml & **60**ml HDPE bottle with screw cap and dose measuring cup.

Gen-M DS Oral Suspension

Gen-M DS Powder for Oral Suspension is available in 30ml HDPE bottle with screw cap and dose measuring cup.

PRESENTATION OF TABLETS:

Gen-M Dispersible Tablets 20mg/120mg

Gen-M (Artemether / Lumefantrine) Dispersible Tablets
20/120mg are available in Alu-Alu Blister pack of 2x8's.

Gen-M Dispersible Tablets 40mg/240mg

Gen-M (Artemether / Lumefantrine) Dispersible Tablets 40/240mg are available in Alu-Alu Blister pack of 8's.

Gen-M Tablets 80mg/480mg

Gen-M (Artemether / Lumefantrine) Tablets 80/480 are available in Alu-Alu Blister pack of 1x6's.

How to use Dispersible Tablets: Dissolve each tablet in half glass of plain water & drink.

Dosage: As directed by the physician.

Instructions: Store below 30°C. Protect from heat, light & moisture. Keep all medicines out of the reach of children.

طریقہ استعمال: ڈسپرسبل ٹیبلٹ کو آدھے گلاس سادہ پانی میں حل کر کے پئیں۔

جین ایم اور جین ایم ڈی ایس سسپنشن تیار کرنے کیلئے

تھوڑا سا اُبلا ہوا ٹھنڈا پانی بوتل میں شامل کریں اور بوتل کو اچھی طرح ہلائیں۔ تا کہ تمام دوا اچھی طرح حل ہو جائے۔
پھر مزید پانی بوتل پر دیئے ہوئے نشان تک شامل کر دیں اور بوتل کو دوبارہ اچھی طرح ہلا لیں۔
تیار شدہ سسپنشن ۱۴ دن کے اندر استعمال کر لیں۔

خوراک: ڈاکٹر کی ہدایت کے مطابق استعمال کریں۔
ہدایات: ۳۰ ڈگری سینٹی گریڈ سے کم درجہ حرارت پر رکھیں۔ روشنی، گرمی اور نمی سے محفوظ رکھیں۔
تمام دوائیں بچوں کی پہنچ سے دور رکھیں۔

For detailed information:

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ISO 9001:2015 ISO 14001:2015 ISO 45001:2018