گولیاں اور پاؤڈر سسپنشن

میلفن® میلفن ڈی ایس®

میلفن فورٹ® میلفن جونئیر®

آرٹیمیتھر، لِیومیفینٹرین

اینٹی - ملیریل

خوراک:

دوا ڈاکٹر کی ہدایات کے مطابق استعمال کریں۔

دوا کو کھانا کھانے کے بعد دُودھ کے ساتھ لیں۔ اس طرح دوا بہتر جذب ہوتی ہے۔

ہدایات:

* دوا کو گرمی، روشنی اور نمی سے محفوظ رکھیں۔
* دوا کو خشک اور ٹھنڈی جگہ پر رکھیں۔
* تمام دوائیں بچوں کی پہنچ سے دور رکھیں۔
* استعمال سے پہلے بوتل کو اچھی طرح ہلا لیں۔
* استعمال کے بعد بوتل کا ڈھکن اچھی طرح بند رکھیں۔
* تیار شدہ سسپنشن کو کمرے کے درجہ حرارت پر رکھیں۔
* تیار شدہ سسپنشن کو ریفریجریٹر میں مت رکھیں۔
* تیار شدہ سسپنشن ۷ دن تک قابلِ استعمال ہے۔

پیشکش:

میلفن گولیاں (۲×۸) بلسٹر پیک میں دستیاب ہیں۔

میلفن ڈی ایس گولیاں (۱×۸) بلسٹر پیک میں دستیاب ہیں۔

میلفن فورٹ گولیاں (۱×۴) بلسٹر پیک میں دستیاب ہیں۔

میلفن جونئیر پاؤڈر سسپنشن ۳۰ ملی لیٹر اور ۶۰ ملی لیٹر رنگدار پلاسٹک بوتل میں دستیاب ہے۔

Manufactured by:

Schazoo Zaka (Pvt) Ltd.

Kalalwala, 20-Km Lahore-Jaranwala Road,
Distt: Sheikhupura, Pakistan.

Tablets & Powder Suspension

Malfan® Malfan DS®

Malfan Forte® Malfan Junior®

Artemether, Lumefantrine

ANTI-MALARIAL

COMPOSITION:

Each Malfan tablet contains:
Artemether Sch. Specs. ..... 20mg.
Lumefantrine Sch. Specs. ..... 120mg.

Each Malfan DS tablet contains:
Artemether Sch. Specs.. ..... 40mg.
Lumefantrine Sch. Specs. ..... 240mg.

Each Malfan Forte tablet contains:
Artemether Sch. Specs. ..... 80mg.
Lumefantrine Sch. Specs. ..... 480mg.

Each (5ml) of reconstituted Malfan Junior suspension contains:
Artemether Sch. Specs. ..... 15mg.
Lumefantrine Sch. Specs. ..... 90mg.

CLINICAL PHARMACOLOGY:
Pharmacokinetics:
Mode of Action:
The site of antiparasitic action of both components is the food vacuole of the malarial parasite, where they are thought to interfere with the conversion of haem, a toxic intermediate produced during haemoglobin breakdown, to the non-toxic haemozoin, malaria pigment.
Lumefantrine is thought to interfere with the polymerisation process, while artemether generates reactive metabolites as a result of the interaction between its peroxide bridge and haem iron. Both artemether and lumefantrine have a secondary action involving inhibition of nucleic acid and protein synthesis within the malarial parasite.
Absorption:
Artemether is absorbed fairly rapidly with peak plasma concentrations reached about 3 hours after dosing. Absorption of lumefantrine, a highly lipophilic compound, starts after a lag period of up to 2 hours, with peak plasma concentration about 6-8 hours after dosing.
Food enhances the absorption of both artemether and lumefantrine. Patients should be encouraged to take the drug with a normal diet as soon as food can be tolerated.
Distribution:
Lumefantrine is highly protein bound (99.7%), the majority being bound to high density lipoproteins. Artemether is highly protein bound to plasma proteins (95.4%) with a large proportion (33%) being bound to α_1 glycoproteins. Dihydroartemisinin is also bound to human plasma proteins (47 to 76%).
Metabolism:
Artemether is rapidly and extensively metabolized (substantial first pass metabolism). Human liver microsomes metabolise artemether to the biologically active main metabolite dihydroartemisinin, predominantly through the enzyme CYP3A4/5. Lumefantrine is N-debutylated, mainly by CYP3A4.

Excretion:
Lumefantrine is eliminated very slowly with a terminal half-life of 2 to 3 days in healthy volunteers and 4 to 6 days in patients with falciparum malaria. Artemether and dihydroartemisinin are rapidly cleared from plasma with elimination half-life of about 2 hours.

INDICATIONS:
Malfan, Malfan DS, Malfan Forte and Malfan Junior are indicated for the treatment of;
- Adults, children and infants with acute, uncomplicated infections due to Plasmodium falciparum or mixed infections including Plasmodium falciparum.
- Malaria infections acquired in areas where the parasite may be resistant to other antimalarials.
- Stand-by emergency treatment for tourists and business travellers.

DOSAGE & ADMINISTRATION:
Artemether and lumefantrine tablets and dry powder suspension should be taken with high fat food or drinks such as milk. Patients should 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.
The treatment should be administered at the time of initial diagnosis or at onset of symptoms.

Tablets:
Adults and children weighing over 34 Kg or more than 12 years of age
A standard 3 days treatment regimen with a total of 6 doses is recommended as follows:
4 Malfan tablets or 2 Malfan DS tablets or 1 Malfan Forte tablet (artemether 80mg and Lumefantirne 480mg) as a single dose at diagnosis and repeated after 8 hours and then same dose should be taken twice daily (morning and evening) on each of the following two days (total course comprises 24 Malfan tablets, 12 Malfan DS tablets and 6 Malfan Forte tablets).

Infants and children weighing 5 Kg to less than 35 Kg and 12 years of age or less
A 6 dose regimen is recommended with artemether 20mg to 60mg and Lumefantirne120mg to 360mg per dose, depending on body weight.
- **Children 5 to 14 Kg**
  1 Malfan tablet or 1/2 Malfan DS tablet (artemether 20mg and Lumefantirne 120mg) at diagnosis and repeated after 8 hours and then same dose should be taken twice daily (morning and evening) on each of the following two days (total course comprises 6 Malfan tablets or 3 Malfan DS tablets.
- **Children 15 to 24 Kg**
  2 Malfan tablets or 1 Malfan DS tablet or 1/2 Malfan Forte tablet (artemether 40mg and Lumefantirne 240mg) as single dose at diagnosis and repeated after 8 hours and then same dose should be taken twice daily (morning and evening) on each of the following two days (total course comprises 12 Malfan tablets or 6 Malfan DS tablets or 3 Malfan Forte tablets).
- **Children 25 to 34 Kg**
  3 Malfan tablets or 1½ Malfan DS tablet (artemether 60mg and Lumefantirne 360mg) at diagnosis and repeated after 8 hours then same dose should be taken twice daily (morning and evening) on each of the following two days (total course comprises 18 Malfan tablets or 9 Malfan DS tablets.

Dry Powder Suspension

Body Weight	Day 1 (0 hour)	Day 2 (24 hour)	Day 3 (48 hour)
5.0 Kg	7 ml	7 ml	7 ml
7.5 Kg	10 ml	10 ml	10 ml
10 Kg	14 ml	14 ml	14 ml
15 Kg	20 ml	20 ml	20 ml

Administered once daily at 0, 24 and 48 hours on days 1, 2 and 3 or as prescribed by physician.

Special populations:
Dosage in elderly patients:
Although no studies have been carried out in the elderly, no special precautions or dosage adjustments are considered necessary in such patients.
Dosage in patients with renal or hepatic impairment:
No specific studies have been carried out in these groups of patients and no specific dose adjustment recommendations can be made for these patients.

New and recrudescent infections in adults, children and infants:
Data for a limited number of patients show that new and recrudescent infections can be treated with a second course of artemether and lumefantrine combination.

CONTRA-INDICATIONS:
Artemether and lumefantrine tablets and dry powder suspension are contraindicated:
- In patients with hypersensitivity to the active substances or any of the excipients.
- During first trimester of pregnancy or during lactation.
- In patients with severe malaria.
- In patients with family history of congenital prolongation of the QTc interval or sudden death.
- In patients taking drugs that are known to prolong the QTc interval (antiarrhythmics, neuroleptics, certain antibiotics, certain non sedating antihistaminics and cisapride).
- In patients with known disturbances of electrolyte balance (hypokalaemia or hypomagnesaemia).
- Patients taking any drug which is metabolized by the cytochrome enzyme CYP2D6 (e.g. Flecainide, Metoprolol, Imipramine, Amitryptyline, Clomipramine).

PRECAUTIONS & WARNINGS:
Use with caution in patients with severe hepatic or renal insufficiency (ECG and blood potassium should be monitored) and in patients refusing food intake as the risk of recrudescence may be greater.

Pregnancy & lactation:
The safe use of artemether and lumefantrine during pregnancy and lactation has not been established, so Malfan, Malfan DS and Malfan Forte treatment should only be considered if the expected benefit to the mother outweighs the risk to the fetus.
Effect on the ability to drive & use machines:
Patients receiving Malfan, Malfan DS and Malfan Forte should be warned that dizziness or fatigue/asthenia might occur and in that case they should not drive or use machines.

DRUG INTERACTIONS:
The combination should not be given concurrently with
- Other antimalarials
- Anti-retroviral drugs
- CYP450 3A4 inhibitor (Ketoconazole)

SIDE EFFECTS:
Artemether and Lumefantrine have been well tolerated, some of the side effects are: Headache, Dizziness, Abdominal pain, Anorexia, Sleep disorder, Palpitation, Cough, Nausea, Vomiting, Diarrhoea, Rash, Pruritis, Arthralgia, Fatigue and Liver function tests increased.

OVERDOSAGE & MANAGEMENT:
In cases of suspected over dosage, symptomatic and supportive therapy should be given as appropriate. ECG and electrolytes (e.g. potassium) should be monitored.

STORAGE CONDITIONS:
- Store in a cool, dry place.
- Protect from heat, light and moisture.
- Keep the cap of suspension bottle tightly closed.
- Reconstituted suspension must be used within 7 days.
- Shake well the reconstituted suspension before use.
- Do not refrigerate the reconstituted suspension, store at room temperature.
- Keep all medicines out of the reach of children.

PACKING:
- Malfan tablets are available in (2 x 8) blister pack.
- Malfan DS tablets are available in (1 x 8) blister pack.
- Malfan *Forte* tablets are available in (1 x 4) blister pack.
- Malfan *Junior* dry powder suspension is available in 30ml and 60ml amber plastic bottle.