MEFLOQUINE Hydrochloride Tablets USP 250 mg

Composition:
Each film coated tablet contains:
Mefloquine Hydrochloride USP....250 mg
Excipients.....q.s.
Approved colour used.

Therapeutic indications
Therapy and chemoprophylaxis of malaria.
Therapy: Mefloquine is especially indicated for therapy of *P. falciparum* malaria in which the pathogen has become resistant to other antimalarial agents.
Following treatment of *P. vivax* malaria with Mefloquine, relapse prophylaxis with an 8- amino-quinoline derivative, for example primaquine, should be considered in order to eliminate parasites in the hepatic phase.
Chemoprophylaxis: Malaria chemoprophylaxis with Mefloquine is particularly recommended for travellers to malarious areas in which multiply resistant *P. falciparum* strains occur.

Posology and method of administration
When chemoprophylaxis with Mefloquine fails, physicians should carefully evaluate which antimalarial to use for therapy.
Chemoprophylaxis
For malaria prophylaxis the stated dose of Mefloquine should be given once weekly, always on the same day.
In order to ensure, before arrival in endemic area, that Mefloquine administration is well tolerated, it is recommended to start chemoprophylaxis with Mefloquine 10 days before departure (i.e. first intake 10 days before departure and 2nd intake 3 days before departure). Subsequent doses should be taken once a week (on a fixed day).
Treatment should be continued for 4 weeks after leaving a malarious area (minimum treatment period 6 weeks). The maximum recommended duration of administration of Mefloquine is 12 months.
The recommended chemoprophylactic dose of Mefloquine is approximately 5 mg/kg bodyweight once weekly. The following dosage schedule is given as a guide:

	Dosage
Adults and children of more than 45 kg bodyweight	1 tablet
Children and adults weighing less than 45 kg 5 – 19 kg 20 – 30 kg 31 – 45 kg	 ¼ tablet ½ tablet ¾ tablet

Curative treatment
The recommended total therapeutic dose of Mefloquine is 20 – 25 mg/kg.
The recommended total therapeutic dosages of Mefloquine tablets relative to body weight are presented in the following table:

Body Weight	**Total dose**
<20 kg *	¼ tablet / 2.5 – 3 kg 1 tablet / 10 – 12 kg
20 – 30 kg	2 – 3 tablets
	> 30 – 45 kg 3 – 4 tablets
	> 45 – 60 kg 4 – 5 tablets
> 60 kg **	6 tablets

Experience with Mefloquine in infants less than 3 months old or weighing less than 5 kg is limited.
** There is no specific experience with total dosages of more than 6 tablets in very heavy patients.
In order to limit the occurrence and severity of adverse reactions, the total therapeutic dose may be split into 2 – 3 doses (e.g. 3 + 1, 3 + 2 or 3 + 2 + 1 tablets) taken 6 – 8 hours apart.
A second full dose should be given to patients who vomit less than 30 minutes after receiving the drug. If vomiting occurs 30 – 60 minutes after a dose, an additional half-dose should be given.
If a full treatment course with Mefloquine does not lead to improvement within 48 – 72 hours, alternative treatments should be considered.
Mefloquine can be given for severe acute malaria after an initial course of intravenous quinine lasting at least 2 – 3 days. Interactions leading to adverse events can largely be prevented by allowing an interval of at least 12 hours after the last dose of quinine.
Artemisinin combination therapy (ACT) is recommended as the standard of care for treatment of *P. falciparum* malaria, regardless of region of acquisition. Mefloquine is a recommended partner molecule for inclusion in ACT.
Elderly
No specific adaptation of the usual adult dosage is required for elderly patients.

Contraindications
- known hypersensitivity to mefloquine or related compounds (e.g. quinine, quinidine), or to any of the excipients contained in the formulation.
- chemoprophylaxis in patients with active depression, a history of depression, generalised anxiety disorder, psychosis, suicide attempts, suicidal ideations and self-endangering behaviour, schizophrenia or other psychiatric disorders, or with a history of convulsions of any origin.
- halofantrine must not be used during mefloquine chemoprophylaxis or treatment of malaria or within 15 weeks after the last dose of mefloquine, due to the risk of a potentially fatal prolongation of the QTc interval.
- in patients with a history of Blackwater fever, a complication of falciparum malaria with massive intravascular haemolysis causing haemoglobinuria.
- in patients with severe hepatic impairment.
- Prophylactic use in patients with severe impairment of liver function should be regarded for the time being as a contraindication as no experience has been gained in such patients.

Fertility, pregnancy and lactation pregnancy
Mefloquine was teratogenic in mice and rats and embryotoxic in rabbits; however, large clinical experience with Mefloquine as prophylactic treatment has not revealed an embryotoxic or teratogenic effect. Data from a limited number of exposed pregnancies indicate no adverse effects of mefloquine on pregnancy or on the health of the foetus/newborn child. To date, no other relevant epidemiological data are available.
Therefore:
- due to the seriousness of malaria during pregnancy, pregnant women or women who wish to become pregnant should be discouraged from travelling in endemic areas. Prophylactic treatment with mefloquine may be considered regardless the term of pregnancy but in the strict respect of the indications.
- use of mefloquine as curative treatment in pregnant women is limited to the treatment of acute uncomplicated malaria when quinine is contra-indicated or in case of Plasmodium falciparum resistance to quinine.
In case of unplanned pregnancy, malaria chemoprophylaxis with Mefloquine is not considered as an indication for pregnancy termination. For use of mefloquine during pregnancy, current national and international guidelines should be consulted.
Breast-feeding
Mefloquine is secreted into the breast milk in small amounts, the activity of which is unknown. As a precautionary measure, mefloquine should be avoided in breast-feeding women. For use of mefloquine in nursing mothers current national and international guidelines should be consulted.

Overdose
Symptoms and signs
In cases of overdosage with mefloquine, the symptoms mentioned under section 4.8 may be more pronounced.
Treatment
Patients should be managed by symptomatic and supportive care following mefloquine overdose. There are no specific antidotes. The use of oral activated charcoal to limit mefloquine absorption may be considered within one hour of ingestion of an overdose. Monitor cardiac function (if possible by ECG) and neuropsychiatric status for at least 24 hours. Provide symptomatic and intensive supportive treatment as required, particularly for cardiovascular disorders. Elimination of mefloquine and its metabolites is limited by haemodialysis.

Storage:
Store below 30ºC in a dry place, protect from light.

Keep medicines out of reach of children.

Presentaion: Blister of 4 Tablets.

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