

Only for the use of Medical Professionals

Meflon[®]

Presentation

Meflon[®] 250mg tablets: Light yellow coloured, round shaped tablet, one side plain and other side with a break line. Each tablet contains Mefloquine 250 mg as Hydrochloride BP.

Indications and uses

- Acute Malaria Infections caused by Mefloquine-susceptible strains of Plasmodium falciparum (both chloroquine- susceptible and resistant strains) or by P. vivax
- Prophylaxis of P. falciparum and P. vivax malaria infections

Dosage and administration

Adult

Malaria prevention: 1 tablet (250 mg) once per week starting 1-2 weeks before departure and continued for 4 weeks after leaving malarious area.

Malaria treatment: 5 tablets (5 x 250mg) in a single dose (up to max. 1.5 gm) or preferably in 2 divided doses 6 to 8 hours apart.

In Children 6 Months and Older

Malaria prevention: Approximately 5 mg/kg body weight once per week (250 mg for children weighing over 45 kg [100 lbs], decreasing in proportion to body weight for children weighing 45 kg or less).

Malaria treatment: 20 to 25 mg/kg body weight which may be split into two doses 6 to 8 hours apart to reduce the occurrence or severity of adverse reactions.

Contra-indications, warnings, etc.

Contraindications: Use of Mefloquine is contraindicated in patients with a known hypersensitivity to Mefloquine or related compounds (e.g. quinine and quinidine). It should not be prescribed for prophylaxis in patients with active depression, a recent history of depression, generalized anxiety disorder, psychosis, or schizophrenia or other major psychiatric disorders, or with a history of convulsions.

Warnings: Mefloquine may cause psychiatric symptoms in a number of patients, ranging from anxiety, paranoia, and depression to hallucinations and psychotic behavior. Rare cases of suicidal ideation and suicide have been reported though no relationship to drug administration has been confirmed. Mefloquine should be used with caution in patients with a previous history of depression.

Concomitant administration of Mefloquine and quinine or quinidine may produce electrocardiographic abnormalities and may increase risk of convulsions.

Precautions: In patients with epilepsy, Mefloquine may increase the risk of convulsions. Caution should be exercised with regard to activities requiring alertness and fine motor coordination such as driving, piloting aircraft and operating machinery. Mefloquine should be used with caution in patients with psychiatric disturbances. In patients with impaired liver function the elimination of Mefloquine may be prolonged, leading to higher plasma levels.

Use in Pregnancy: There is no adequate and well-controlled study in pregnant women. However, clinical experience with Mefloquine has not revealed an embryotoxic or teratogenic

effect. Mefloquine should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus.

Use in Nursing Mothers: Mefloquine is excreted in breast milk in small amounts. the activity of which is unknown. Because of the potential for serious adverse reactions in nursing infants form Mefloquine. a decision should be made whether to discontinue the drug taking into account the importance of the drug to the mother.

Geriatric Use: Experiences have not identified differences in responses between the elderly and younger patients.

Side-effects: Among subjects who received Mefloquine for prophylaxis of malaria, following side-effects was observed:

- The most frequently observed sied-effects were vomiting, dizziness, syncope, extrasystoles and other complaints affecting less than 1%.
Among subjects who received Mefloquine for treatment, following side-effects was observed:
- The most frequently observed side-effects included : dizziness, myalgia, nausea, fever, headache, vomiting, chills, diarrhoea, skin rash, abdominal pain fatigue, loss of appetite, and tinnitus

Overdosage: In cases of overdosage with Mefloquine, the symptoms may be more pronounced. The following procedure is recommended in case of overdosage:

- Induce vomiting or perform gastric lavage, as appropriate.
- Monitor cardiac function (if possible by ECG), neurologic and psychiatric status for at least 24 hours.
- Provide Symptomatic and intensive supportive treatment as required, particularly of cardiovascular disturbance.
- Treat vomiting or diarrhoea with standard fluid therapy.

Pharmaceutical precautions

Store in a cool dry place. Protect from light.

Package quantities

Meflon[®] 250 mg tablets: Container of 5 tablets.

® Registered Trade Mark



ACI Limited

Narayanganj, Bangladesh