anxiety, depression, mood swings, panic attacks, memory impairment, confusion, hallucinations. More severe neuropsychiatric disorders have been reported such as: sensory and motor disturbances and telogen effluvium (loss of resting hair). Seizures have also been reported.

Among subjects who received mefloquine for treatment, the most frequently observed adverse effects were gastrointestinal (nausea, vomiting, diarrhea) and psychiatric (headache, insomnia, irritability, emotional lability). Other adverse effects include skin reactions (rash, pruritus, photosensitivity), auditory disturbances (tinnitus, hearing loss), and neurologic effects (dizziness, vertigo).

PRECAUTIONS

Pregnancy Category B

Mefloquine is not approved for use in pregnant women. However, in a study in a few subjects, low concentrations (3% to 4%) of mefloquine were excreted in human milk. Administration of 250 mg/week of mefloquine to nursing women resulted in milk concentrations of about 3% at steady-state. It is not known whether mefloquine is excreted in human milk, but it is known that the drug is excreted in human milk in animals.

Fertility studies in rats at doses of 5, 20, and 50 mg/kg/day of mefloquine showed no evidence of any impairment of fertility. In a study in a few subjects, low concentrations (3% to 4%) of mefloquine were excreted in human milk. Administration of 250 mg/week of mefloquine to nursing women resulted in milk concentrations of about 3% at steady-state. It is not known whether mefloquine is excreted in human milk, but it is known that the drug is excreted in human milk in animals.

Drug Interactions

Mefloquine does not interact with other drugs in a manner that desensitizes P-glycoprotein. Thus, concomitant administration of mefloquine does not affect the disposition of warfarin, phenytoin, valproate, or digoxin. However, the drug has no effect against the exoerythrocytic stages of the Plasmodium species. Therefore, prophylaxis might be different from one area to another. For example, resistance of P. falciparum to chloroquine (see WARNINGS) may be expected in some areas.

Mefloquine does not inhibit or induce the CYP 450 enzyme system. Thus, concomitant administration of mefloquine does not affect the disposition of rifampin. However, the drug has no effect against the exoerythrocytic stages of the Plasmodium species. Therefore, prophylaxis might be different from one area to another. For example, resistance of P. falciparum to chloroquine (see WARNINGS) may be expected in some areas.

Although clearance of mefloquine may increase in late pregnancy, in general, pregnancy has no influence on the disposition of mefloquine. In women treated for malaria, the plasma concentration of mefloquine is usually lower than the concentration in nonpregnant women treated for malaria. However, the drug has no effect against the exoerythrocytic stages of the Plasmodium species. Therefore, prophylaxis might be different from one area to another. For example, resistance of P. falciparum to chloroquine (see WARNINGS) may be expected in some areas.

Elimination

The absolute oral bioavailability of mefloquine has not been determined since an alternative malaria treatment considered if improvement is not observed within a reasonable period.

The mechanism of action of mefloquine is unknown. However, the drug has no effect against the exoerythrocytic stages of the Plasmodium species. Therefore, prophylaxis might be different from one area to another. For example, resistance of P. falciparum to chloroquine (see WARNINGS) may be expected in some areas.

The plasma elimination half-life of mefloquine is about 30 minutes. The absolute bioavailability of mefloquine is about 98%.

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Stereoselective passage of mefloquine through the blood brain barrier in the rat.

Mefloquine Hydrochloride Tablets USP, 250 mg are available as white, oval-shaped, flat-faced.

20 to 30 kg: 1/2 tablet

The safety and effectiveness of mefloquine to treat malaria in pediatric patients below the age of

and alternative malaria treatment considered if improvement is not observed within a reasonable

additional half-dose should be given. If vomiting recurs, the patient should be monitored closely

). If a significant loss of drug product is observed or suspected

Treatment.

If a full-treatment course with mefloquine does not lead to improvement within 48 to 72 hours,

should not exceed the adult dose.

taken 6 to 8 hours apart may reduce the occurrence or severity of adverse effects. The pediatric dose

Treatment of mild to moderate malaria in pediatric patients caused by mefloquine-susceptible strains

PRECAUTIONS, Drug Interactions

main meal. To reduce the risk of malaria after leaving an endemic area, prophylaxis must be continued

weekly doses should be taken regularly, always on the same day of each week, preferably after the

plasma concentration showed CNS penetration of mefloquine, with a 30-50 fold greater brain/plasma

observed. They occurred in 9% of rats studied.

ANIMAL TOXICOLOGY

plasma and urine levels of mefloquine were significantly lower than in similar human liver pellets. In

and retinal edema. Similar but less severe lesions were observed in 80% of female and

30 mg/kg/day had ocular lesions in both eyes characterized by retinal degeneration, opacity of

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Mefloquine Hydrochloride
Medication Guide

What is the most important information I should know about mefloquine?
Mefloquine is a prescription medicine used to prevent and treat malaria. Malaria can be life-threatening, but it is not always deadly. Mefloquine is only one choice for preventing and treating malaria. It is important that you read the entire Medication Guide for additional information on mefloquine.

How should I take mefloquine?
You need to take malaria prevention medicine every day while you are in a malaria area, and after you return from a malaria area, for 7 days. Mefloquine is also taken to prevent malaria while you are already in a malaria area. Do not take mefloquine to treat malaria. Do not use mefloquine if you have any of the conditions listed above.

What should I tell my doctor before taking mefloquine?
Before you start taking mefloquine, tell your doctor if you have or have had a mental or emotional problem. Do not use mefloquine if you have any of the conditions listed above.

Who should not take mefloquine?
If you are allergic to quinine, mefloquine or quinidine, you should not take mefloquine.

What are the possible side effects of mefloquine?
Some people who take mefloquine think about suicide (putting an end to their life). Some people who were taking mefloquine committed suicide. It is not known if mefloquine was responsible for those suicides. You should contact your doctor right away if you or someone else is thinking about suicide. Symptoms of serious mental problems may include:
• feeling restless, unusual behavior or feeling confused
• depression or had depression recently
• anxiety disorder, schizophrenia, or bipolar disorder
• loss of balance
• a feeling that you or things around you are not real
• inability to move or speak

Mefloquine can cause serious side effects, including:
• QT prolongation. Your heart may beat too slow or stop. QT prolongation can cause convulsions (seizures) in people who already have seizures (epilepsy). Convulsions can cause you to hurt yourself. People who have heart problems (problems with the electrical system of your heart, called Qt prolongation) may be more likely to have convulsions while taking mefloquine. QT prolongation can cause you to have a heart attack. QT prolongation can cause you to have serious heart problems (problems with the electrical system of your heart called QT prolongation)
• loss of balance (dizziness)
• inability to move or speak
• inability to move

Information Wallet card
For current labeling information, please visit https://www.fda.gov/drugsatfda
common side effects

If you vomit after taking mefloquine, contact your doctor to see if you should take another dose. Call your doctor for medical advice about what to do if you vomit more than once or if you vomit after returning from a malaria area. FDA at 1-800-FDA-1088.

What should I avoid while taking mefloquine?

Avoid activities such as driving a car or using heavy machinery or other activities needing mental alertness or physical coordination (such as playing sports) until you know how mefloquine affects you. You may feel dizzy or lose your balance. This could happen for months or years after you stop taking mefloquine and can be permanent in some cases. See "What are the possible side effects of mefloquine?"

How should I store mefloquine?

Store mefloquine between 20°C to 25°C (68°F to 77°F) in a tightly closed container.

Safely throw away medicine that is out of date or no longer needed.

Before using mefloquine, tell your doctor if you:

• have breathing problems, such as asthma, or hay fever
• are breastfeeding or plan to breastfeed. Call your healthcare provider right away if you have any side effect that bothers you or that does not go away. These are not all the possible side effects. This Medication Guide summarizes the most important information about mefloquine. If you would like more information, ask your doctor or pharmacist. This label may not be the latest approved by FDA. For current labeling information, please visit https://www.fda.gov/drugsatfda