Mefloquine Hydrochloride Tablets USP are indicated for the prophylaxis of malaria in areas where chloroquine-resistant P. falciparum is not known to be present. It is also indicated for the treatment of malaria caused by susceptible strains of Plasmodium falciparum and P. vivax, P. ovale, or P. malariae. Mefloquine is not effective against infections caused by Plasmodium knowlesi (see CLINICAL PHARMACOLOGY: Antigenic Variation and Resistance). However, the drug has no effect against Plasmodium vivax, P. ovale, and P. malariae when they are taking mefloquine. The complete text of the Medication Guide and information wallet card is reprinted at the end of this document.

Patients should be advised:

• When they are taking mefloquine committed suicide. It is not known if mefloquine causes suicide. The complete text of the Medication Guide and information wallet card is reprinted at the end of this document.

Before you start taking mefloquine, read the information wallet card that has been written for you. Ask your doctor or pharmacist to explain any of the information or if you have any questions about what you are reading.

What is mefloquine hydrochloride USP?

Mefloquine hydrochloride USP is an antimalarial agent available as 250 mg tablets of mefloquine hydrochloride. Mefloquine hydrochloride USP should be taken orally as a single dose for malaria prophylaxis or as a single dose to treat malaria. Mefloquine hydrochloride USP is a World Health Organization (WHO) recommended drug for the treatment of multidrug-resistant malaria.

How should I take mefloquine hydrochloride USP?

Mefloquine hydrochloride USP tablets should be swallowed whole. Mefloquine hydrochloride USP tablets should be taken as a single dose. Take mefloquine hydrochloride USP tablets with at least one cup (8 ounces) of water. It is important to take mefloquine hydrochloride USP with food or immediately after meals to reduce stomach upset. However, it may also be taken 1 hour before or 4 hours after a meal.

What should I tell my doctor before taking mefloquine hydrochloride USP?

Before you start taking mefloquine hydrochloride USP, tell your doctor if you have any of the following conditions:

• Neurologic Adverse Reactions

Neurologic Adverse Reactions

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Neurologic Adverse Reactions
What are the possible side effects of mefloquine?

• Skin:
  - Rash
  - Itching
  - Severe pruritus

• Muscular:
  - Muscle weakness
  - Muscle cramps
  - Myalgia
  - Arthralgia

• Gastrointestinal:
  - Nausea
  - Vomiting
  - Diarrhea
  - Abdominal pain

• Hematologic:
  - Thrombocytopenia
  - Anemia

• Nervous System:
  - Convulsions (seizures)
  - Dizziness
  - Fatigue
  - Headache
  - Mood changes
  - Depression
  - Feeling restless
  - Unusual behavior
  - Feeling confused
  - Hallucinations
  - Seeing or hearing things that are not there

• Visual:
  - Seeing light flashes
  - Seeing spots

• Other:
  - Light-headedness
  - Difficulty breathing
  - Sweating
  - Changes in vision

• QT Prolongation:
  - QT prolongation

• Inhibit P-glycoprotein:
  - Promethazine
  - Chlorpromazine
  - Other phenothiazines
  - Diltiazem
  - Amiodarone
  - Disopyramide

• Other:
  - Pruritus
  - Asthenia
  - Transient hair loss (effluvium)

In pediatric patients, the administration of mefloquine for the treatment of malaria has been associated with a higher incidence of pruritus, asthenia, and transient hair loss compared to adults. The effect of mefloquine on the activity of which is unclarified.

Geriatric Use

The effects of mefloquine in elderly patients have not been established. However, the disease and its severity may increase with age, and older patients may be more sensitive to the effects of mefloquine. Therefore, mefloquine should be used with caution in elderly patients.

Malaria Treatment in Pediatric Patients

Treatment of mild to moderate malaria in pediatric patients caused by mefloquine-resistant strains of Plasmodium falciparum or by P. vivax:

• Start prophylaxis 2 to 3 weeks prior to departure, in order to ensure that the combination of drugs is well tolerated (see Pharmacokinetics). The combination of drugs is well tolerated. The combination of drugs is well tolerated.

• Should therefore be completed at least 3 days before the first dose of mefloquine hydrochloride tablets USP.

• The occurrence or attenuation of immunization cannot be excluded. Vaccinations with attenuated live bacteria should therefore be completed at least 3 days before the first dose of mefloquine hydrochloride tablets USP.

• Administration of mefloquine to indigenous populations in malaria-endemic areas should therefore be completed at least 3 days before the first dose of mefloquine hydrochloride tablets USP.

• May be more pronounced. The occurrence or attenuation of immunization cannot be excluded. Vaccinations with attenuated live bacteria should therefore be completed at least 3 days before the first dose of mefloquine hydrochloride tablets USP.

• Among subjects who received mefloquine for prophylaxis of malaria, the most frequent adverse experience was pruritus. Among subjects who received mefloquine for prophylaxis of malaria, the most frequent adverse experience was pruritus.

• Dizziness, syncope, extrasystoles, and an increase in mefloquine plasma levels may be more pronounced. Dizziness, syncope, extrasystoles, and an increase in mefloquine plasma levels may be more pronounced.

• Mefloquine is excreted in human milk in small amounts, the activity of which is unclarified. Mefloquine is excreted in human milk in small amounts, the activity of which is unclarified.

• Mutagenesis:
  - Mutagenicity in bacteria
  - Mice
  - Rats

• Substrates and Inhibitors of P-glycoprotein:
  - Methotrexate
  - Chemotherapeutic agents
  - Neuroleptics
  - Opioids
  - Cimetidine
  - Verapamil
  - HMG-CoA reductase inhibitors

• Storage:
  - Protect from moisture and light.

• Avoid exposure of eyes to the eyes of mefloquine. Avoid exposure of eyes to the eyes of mefloquine.
Mefloquine Hydrochloride Tablets USP

Important: You need to take malaria prevention medicine before you travel to a malaria area, and after you return from a malaria area, and if you are in a malaria area.

Important: Mefloquine may cause serious side effects, including:

4. Problems with your heart's electrical system.
5. Problems with your blood clots.
6. Problems with your body's nervous system.

Important: You should not take mefloquine if you have:

If you have any of these serious mental problems, or you develop any of these symptoms after you start taking mefloquine, call your doctor immediately.

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If you have any of these serious mental problems, or you develop any of these symptoms after you start taking mefloquine, call your doctor immediately.
The most common side effects in people who take mefloquine for malaria prevention include:

- Drowsiness
- Fatigue
- Stomach pain
- Fever
- Weakness
- Itching
- Light-colored bowel
- Loss of appetite
- Nausea
- Vomiting
- Diarrhea

What should I avoid while taking mefloquine?

Avoid activities that require alertness and careful movements (fine motor coordination) until you know how mefloquine affects you. You may feel dizzy. Do not drive, operate heavy machinery, or do other activities that require alertness and careful movements. You may feel dizzy.

What should I do if I miss a dose?

If you are taking mefloquine for the prevention of malaria, you do not need to take a different dose for the missed dose.

How should I take mefloquine?

Mefloquine hydrochloride tablets USP should be taken once a week starting 4 weeks before you travel to a malaria area.

If you are taking mefloquine for the prevention of malaria, you do not need to take a different dose for the missed dose. You do not need to take mefloquine every day. You do not need to have your eyes checked to see if you need to have your dose changed.

What are ingredients in mefloquine?

The active ingredient of mefloquine is mefloquine hydrochloride USP. The inactive ingredients are calcium-ammonium alginate, colloidal silicon dioxide, croscryl cellulose, crosclycystine cellulose, crospovidone, lactose (regular), magnesium stearate, methylcellulose, microcrystalline cellulose, povidone, starch, and talc.

What is the possible side effects of mefloquine?

The most common side effects in people who take mefloquine for malaria prevention include:

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- Fever
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- Itching
- Light-colored bowel
- Loss of appetite
- Nausea
- Vomiting
- Diarrhea

How should I take mefloquine?

- Take mefloquine exactly as your doctor tells you to take it. Do not change the way you take mefloquine without talking to your doctor.
- You can take mefloquine with or without food.
- You can take mefloquine just before you go to bed.
- You can take mefloquine once a week starting 4 weeks before you travel to a malaria area.

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