Mefloquine Hydrochloride Tablets USP

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# Mefloquine may cause neuropsychiatric adverse reactions that can persist after mefloquine has been discontinued. Mefloquine should not be

# should not be prescribed for prophylaxis in patients with major psychiatri During prophylactic use, if psychiatric or neurologic symptoms occur, the dru discontinued and an alternative medication should be substituted (see WARNINGS). DESCRIPTION DESCHIPTION Mefloquine Hydrochloride Tablets USP are an antimalarial agent available as 250 mg tablets of mefloquine hydrochloride (equivalent to 228 mg of the free base) for oral administration. Mefloquine hydrochloride USP is a 4-quinolinemethanol derivative with the specific chemical of (R¹, S¹)-(a-) o-2-piperidinyl-2.8-bis (trifluoromethyl)-4-quinolinemethanol hydrochlori is a 2-aryl substituted chemical structural analog of quinine. The drug is a white to almost crystalline compound, slightly soluble in water. The structural formula is as follows:

# \_CF<sub>3</sub>

The inactive ingredients are colloidal silicon dioxide, corn starch, crospovidone, lactose monohydrate magnesium stearate, microcrystalline cellulose, pregelatinized starch, poloxamer and talc. CLINICAL PHARMACOLOGY Pharmacokinetics

M.W.: 414.78

 $\mathsf{C}_{17}\mathsf{H}_{16}\mathsf{F}_{6}\mathsf{N}_{2}\mathsf{O}.\mathsf{HCI}$ 

Pharmacokinetics

Absorption: The absolute oral bioavailability of mefloquine has not been determined since an intravenous formulation is not available. The bioavailability of the tablet formation compared with an oral solution was over 85%. The presence of food significantly enhances the rate and extent of absorption, leading to about a 40% increase in bioavailability. In healthy volunteers, plasma concentrations peak 6 to 24 hours (median, about 17 hours) after a single dose of mefloquine. In a similar group of volunteers, maximum plasma concentrations in moçL are roughly equivalent to the dose in milligrams (for example, a single 1000 mg dose produces a maximum concentration of about 1000 mgc/L, in healthy volunteers, a dose of 250 mg once weekly produces maximum steady-state plasma concentrations of 1000 to 2000 mgc/L, which are reached after 7 to 10 weeks. Distribution: In healthy adults, the apparent volume of distribution is approximately 20 L/k indicating extensive tissue distribution. Mefloquine may accumulate in parasitized erythrocyte Experiments conducted *in vitro* with human blood using concentrations between 50 and 1000 mg/m showed a relatively constant erythrocyte-to-plasma concentration ratio of about 2 to 1. equilibrium reached in less than 30 minutes was found to be reversible. Protein binding is about 98° 20 L/ka.

lefloquine crosses the placenta. Excretion into breast milk appears to be minimal (see **PRECAUTIONS**, **ursing Mothers**). Metabolism: Mefloquine is extensively metabolized in the liver by the cytochrome P451 In vitro and in vivo studies strongly suggested that CYP3A4 is the major isoform involved.

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Two metabolites of melfoquine have been identified in humans. The main metabolite, 2.8-bistrilluoromethyl-4-quinoline carboxylic acid, is inactive in Plasmodium fatciparum. In a study in healthy volunteers, the carboxylic acid metabolite appeared in plasma 2 to 4 hours after a single oral dose. Maximum plasma concentrations of the metabolite, which were about 50% higher than those of melfoquine, were reached after 2 weeks. Thereafter, plasma levels of the main metabolite and melfoquine declined at a similar rate. The area under the plasma concentration-time curve (AUC) of the main metabolite was 3 to 5 times larger than that of the parent drug. The other metabolite, an alcohol, was present in minute quantities only.

Elimination: In several studies in healthy adults, the mean elimination half-life of mefloquine varied between 2 and 4 weeks, with an average of about 3 weeks. Total clearance, which is essentially heaptic, is in the order of 30 mL/min. There is evidence that mefloquine is excreted mainly in the bite and feess. In volunteers, urinary excretion of unchanged mefloquine and its main metabolite under the stady-state condition accounted for about 9% and 4% of the dose, respectively. Concentrations of other metabolites could not be measured in the urine.

Pharmacokinetics in Special Cinicial Situations: Children and the Elderty. No relevant age-related Pharmacokinetics in Special Clinical Situations: Children and the changes have been observed in the pharmacokinetics of mello children has been extrapolated from the recommended adult dose ren and the Elderly: No rele s of mefloquine. Therefore,

No pharmacokinetic studies have been performed in patients with renal insufficiency since only a small proportion of the drug is eliminated renally. Mefloquine and its main metabolite are not appreciably removed by hemodalysis. No special chemoprophyladic dosage adjustment are indicated for dialysis patients to achieve concentrations in plasma similar to those in healthy persons. Although clearance of mefloquine may increase in late pregnancy, in general, pregnancy clinically relevant effect on the pharmacokinetics of mefloquine.

Pharmacokinetic differences have been observed between various ethnic populations. In practice, however, these are of minor importance compared with host immune status and sensitivity of the parasite.

During long-term prophylaxis (>2 years), the trough concentrations and the elimination half-life mefloquine were similar to those obtained in the same population after 6 months of drug use, whi is when they reached steady-state.

clinically relevant effect on the pharmacokinetics of mefloquine.

The pharmacokinetics of mefloquine may be altered in acute malaria.

In vitro and in vivo studies showed no hemolysis associated with glucose-6-phosphate dehydrogena deficiency (see ANIMAL TOXICOLOGY). Microbiology

Mechanism of Action: Mefloquine is an antimalarial agent which acts as a blood schizonticide. Its exact mechanism of action is not known. Activity In Vitro and In Vivo: Mefloquine is active against the erythrocytic stages of Plasmodium species (see INDICATIONS AND USAGE). However, the drug has no effect against the excerythrocytic (hepatic) stages of the parasite. Mefloquine is effective against malaria parasites resistant to chloroquine (see INDICATIONS AND USAGE).

Drug Resistance: Strains of P. Palciparum with decreased susceptibility to melloquine can be selected in vitro or in vivo. Resistance of P. Palciparum to melloquine has been reported in areas of multi-drug resistance in South East Asia. Increased incidences of resistance have also been reported in other parts of the world.

Cross-resistance: Cross-resistance between melloquine and halofantrine and cross-resistance between melloquine and quilnine have been observed in some regions.

Deliveren in Hendiquine share under lave even in some regions.

INDICATIONS AND USAGE

Treatment of Acute Malaria Infections

Melfoquine Hyrocholriofic abliets USP are indicated for the treatment of mild to moderate acute

malaria caused by melfoquine-susceptible strains of P. Alaciparum (both chloroquine-susceptible and

resistant strains) or by Plasmodium vivax. There are insufficient clinical data to document the effect

of melfoquine in malaria caused by P. ovale or P. malariae. **Note:** Patients with acute *P. vivax* malaria, treated with mefloquine, are at high risk of relapse because mefloquine does not eliminate excerythrocytic (hepatic phase) parasites. To avoid relapse, after initial treatment of the acute infection with mefloquine, patients should subsequently be treated with an 8-aminoquinoline derivative (e.g., primaquine).

malaria infections, including prophylaxis of chloroquine-resistant strains of *P. aliciparum*.

CONTRAINDICATIONS

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

WARNINGS

In case of life-threatening, serious or overwhelming malaria infections due to *P. falciparum*, patients should be treated with an intravenous antimalarial drug. Following completion of intravenous treatment, mefloquine may be given to complete the course of therapy.

Oto Interval Prolongation and Drug Interactions
Halofantrine should not be administered with mefloquine or within 15 weeks of the last dose of mefloquine due to the risk of a potentially fatal prolongation of the OTc interval (see CLINICAL PHARMACOLOGY, Pharmacokinetics, *Elimination*).

Ketoconazole should not be administered with mefloquine or within 15 weeks of the last dose of mefloquine due to the risk of a potentially fatal prolongation of the OTc interval. Ketoconazole increases plasma concentrations and elimination half-life of mefloquine dumper and preconazole increases plasma concentrations and elimination half-life of mefloquine diventions, Drug Interactions).

Concomitant administration of mefloquine and quinine or quinidine may produce electrocardiographic

Prevention of Malaria Melloquine Hydrochloride Tablets USP are indicated for the prophylaxis of *P. falciparum* and *P. vivax* malaria infections, including prophylaxis of chloroquine-resistant strains of *P. falciparum*.

Psychiatric and Neurologic Adverse Reactions
Mefloquine may cause neuropsychiatric adverse reactions in adults and children. Neuropsychiatric
symptoms can be difficult to identify in children. Therefore, vigilance is required to monitor for the
occurrence of these symptoms, especially in nonverbal children. Psychiatric Adverse Reactions
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Psychiatric Adverse Reactions
Psychiatric symptoms ranging from anxiety, paranoia, and depression to hallucinations and psychotic behavior can occur with mefloquine use. Symptoms may occur early in the course of mefloquine use. In some cases, these symptoms have been reported to continue for months or years after mefloquine has been stopped. Cases of suicidal ideation and suicide have been reported. Mefloquine should not be prescribed for prophylaxis in patients with active depression, generalized anxiety disorder, psychosis, or schizophrenia or other major psychiatric disorders. Mefloquine should be used with cau

During prophylactic use, the occurrence of psychiatric symptoms such as acute anxiety, depression, restlessness or confusion suggest a risk for more serious psychiatric disturbances or neurologic adverse reactions. In these cases, the drug should be discontinued and an alternative medication should be substituted.

Neurologic Adverse Reactions
Neurologic symptoms such as dizziness or vertigo, tinnitus, and loss of balance have been reported. These adverse reactions may occur early in the course of mefloquine use and in some cases have been reported to continue for months or years after mefloquine has been stopped. Dizziness or vertigo, tinnitus, and loss of balance have been reported to be permanent in some cases. During prophylactic use, if neurologic symptoms occur, the drug should be discontinued and an alternative medication should be substituted.

Caution should be exercised with regard to activities requiring alertness and fine motor coordination, such as driving, piloting aircraft, operating machinery, and deep-sea driving, while symptoms persist. Melfoquine may increase the risk of convulsions in patients with epilepsy. The drug should therefore be prescribed only for curative treatment in such patients and only if there are compelling medical reasons for its use (see PRECAUTIONS: Drug Interactions).

Concomitant administration of mefloquine and quinine or chloroquine may increase the risk of convulsions.

Use in Patients with Hepatic Impairment In patients with impaired liver function the elimination of mefloquine may be prolonged, leading to higher plasma levels and a higher risk of adverse reactions.

PRECAUTIONS
Hypersensitivity Reactions
Hypersensitivity reactions have been reported with mefloquine use.

Concomitant administration of mefloquine and quinine or quinidine may produce electrocardiographic abnormalities.

Ingrier plasma eversia and a higher risk of adverse featurions.

Long-Term Use

This drug has been administered for longer than one year. If the drug is to be administered for a prolonged period, periodic evaluations including liver function tests and evaluations for neuropsychiatric effects should be performed (see WARNINGS and ADVERSE REACTIONS, Postmarketing). Periodic ophthalmic examinations are recommended. Retinal abnormalities seen in humans with long-term chloroquine use have not been observed with mefloquine use, however, long-term feeding of mefloquine to rats resulted in dose-related ocular lesions (retinal degeneration, retinal edema and lenticular opacity at 12.5 mg/kg/day and higher) (see ANIMAL TOXICOLOGY). Unification opacity at 12.5 mg/kg/day and higher) (see ANIMAL TOXICULUGT).

Cardiac Effects
Parenteral studies in animals show that mefloquine, a myocardial depressant, possesses 20% of the anti-fibrillatory action of quinidine and produces 50% of the increase in the PR interval reported with quinine. The effect of mefloquine on the compromised cardiovascular system has not been evaluated. However, transitory and clinically slighter EGG alterations have been reported during the use of mefloquine; alterations included sinus bradycardia, sinus arrhythmia, first degree AV-block prolongation of the QTc interval and abnormal T waves (see also cardiovascular effects under PRECAUTIONS, Drug Interactions and ADVERSE REACTIONS). The benefits of mefloquine therapy should be weighed against the possibility of adverse effects in patients with cardiac disease.

Drug Resistance and Cross-Resistance
Geographical drug resistance patterns of P. falciparum occur and the preferred choice of malaria prophylaxis might be different from one area to another. For example, resistance of P. falciparum to mefloquine has been reported, predominantly in areas of multi-drug resistance in South-East Asia. Cross-resistance between mefloquine and quinine have been observed in some regions.

Agranulocytosis and Aplastic Anemia

Agranulocytosis and Aplastic Anemia
Cases of agranulocytosis and aplastic anemia have been reported (see ADVERSE REACTIONS). Laboratory Tests
Periodic evaluation of hepatic function should be performed during prolonged prophylaxis.

Territoric evaluation or neglatic function should be performed unting protonings propriyaxis. 
Information for Patlents
Medication Guide: As required by law, a mefloquine hydrochloride tablets Medication Guide is 
supplied to patients when mefloquine is dispensed. An information wallet card is also supplied to 
patients when mefloquine is dispensed. Patients should be instructed to read the Medication Guide 
when mefloquine is received and to carry the information wallet card with them when they are taking 
mefloquine. The complete texts of the Medication Guide and information wallet card are reprinted 
at the end of this document.

Patients Should he advised:

that mefloquine hydrochloride tablets are being prescribed to help prevent or treat this serious

that some patients are unable to take this medication because of side effects, including dizziness or vertigo and loss of balance, and it may be necessary to change medications. In some patients it has been reported that these symptoms may continue for months or years after discontinuation of the drug and can be permanent in some cases;

Patients should be advised:

that insomnia may occur

infection;

that malaria can be a life-threatening infection

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 in the whole when the work of the whole which is the whole
 in the whole whole whole
 in an endemic area; that if the patients experience psychiatric adverse reactions such as acute anxiety, depression, restlessness or confusion, or suicidal ideation, the drug should be discontinued and an alternative medication should be substituted; that no chemoprophylactic regimen is 100% effective, and protective clothing, insect repellents, and bed nets are important components of malaria prophylaxis; to seek medical attention for any febrile illness that occurs after return from a malaria area and to inform their physician that they may have been exposed to malaria. Drug Interactions

Drug-drug interactions with mefloquine have not been explored in detail. There is one report of cardiopulmonary arrest, with full recovery, in a patient who was taking a beta blocker (propranolol) (see PRECAUTIONS, Cardiac Effects). The effects of mefloquine on the compromised cardiovascular system have not been evaluated. The benefits of mefloquine therapy should be weighed against the possibility of adverse effects in patients with cardiac disease.

Halofantrine
Halofantrine
Halofantrine should not be administered with mefloquine or within 15 weeks of the last dose of mefloquine due to the risk of a potentially fatal prolongation of the QTc interval (see WARNINGS).

Ofter Antimalarial Drugs
Concomitant administration of melloquine and other related antimalarial compounds (e.g., quinine, quinidine and chloroquine) may produce electrocardiographic abnormalities and increase the risk of convulsions (see WARMINGS). If these drugs are to be used in the initial treatment of severe malaria, melloquine administration should be delayed at least 12 hours after the last dose. Clinically significant OTc prolongation has not been found with mefloquine alone.

OTc prolongation has not been found with mefloquine alone. 
Ketoconazole (Potent Inhibitor of CYP3A4)

Coadministration of a single 500 mg oral dose of mefloquine with 400 mg of ketoconazole once daily for 10 days in 8 healthy volunteers resulted in an increase in the mean C<sub>max</sub> and AUC of mefloquine by 64% and 79%, respectively, and an increase in the mean elimination half-life of mefloquine from 322 hours to 448 hours. Ketoconazole should not be administered with mefloquine or within 15 weeks of the last dose of mefloquine due to the risk of a potentially fatal prolongation of the QTc interval (see WARNINGS).

Other Drugs that Prolong the QTc Interval

Other Drugs that Prolong the QTc Interval

Coadministration of other drugs known to alter cardiac conduction (e.g., anti-arrhythmic or beta-adrenergic blocking agents, calcium channel blockers, antihistamines or H<sub>1</sub>-blocking agents, tricyclic antidepressants and phenothisiznies) might also contribute to a prolongation of the QTc interval. There are no data that conclusively establish whether the concomitant administration of mefloquine and the above listed agents has an effect on cardiac function.

Anticonvulsants

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Anticonvulsants
In patients taking an anticonvulsant (e.g., valproic acid, carbamazepine, phenobarbital or phenytoin), the concomitant use of melloquine may reduce seizure control by lowering the plasma levels of the anticonvulsant. Therefore, patients concurrently taking anti-seizure medication and melloquine should have the blood level of their anti-seizure medication monitored and the dosage adjusted appropriately (see PRECAUTIONS).

appropriately (see PRECOUNTS).

Vaccines

When mefloquine is taken concurrently with oral live typhoid vaccines, 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 tables.

Ritampin (Potent Inducer of CYP3A4)

Coadministration of a single 500 mg oral dose of mefloquine and 600 mg of ritampin once daily for 7 days in 7 healthy Thai volunteers resulted in a decrease in the mean C<sub>max</sub> and AUC of mefloquine by 19% and 68%, respectively, and a decrease in the mean elimination half-life of mefloquine from 305 hours to 113 hours. Ritampin should be used cautiously in patients taking mefloquine.

Inhibitors and Inducers of CYP3A4

305 hours to 113 hours. Rifampin should be used cautiously in patients taking mefloquine. 
Inhibitors and Induces of CYP3A4
Mefloquine does not inhibit or induce the CYP 450 enzyme system. Thus, concomitant administration of mefloquine hydrochloride tablets and substrates of the CYP 450 enzyme system is not expected to or result in a drug interaction. However, mefloquine is metabolized by CYP3A4 and inhibitors of CYP3A4 may modify the pharmacokinetics/metabolism of mefloquine, leading to an increase in mefloquine plasma concentrations and potential risk of adverse reactions. Therefore, mefloquine hydrochloride tablets should be used with caution when administered concomitantly with CYP3A4 inhibitors. Similarly, inducers of CYP3A4 may modify the pharmacokinetics/metabolism of mefloquine, leading to a decrease in mefloquine plasma concentrations and potential reduction in efficacy of mefloquine hydrochloride tablets. Therefore, mefloquine hydrochloride tablets should also be used with caution when administered concomitantly with CYP3A4 inducers.

Substrates and Inhibitors of Parkoconotein

Substrates and Inhibitors of P-glycoprotein
It has been shown in vitro that melfloquine is a substrate and an inhibitor of P-glycoprotein. Therefore,
drug-drug interactions could also occur with drugs that are substrates or are known to modify the
expression of this transporter. The clinical relevance of these interactions is not known to date.

Other Potential Interactions

No other drug interactions are known. Nevertheless, the effects of mefloquine on travelers receiving concomitant medications, particularly diabetics or patients using anticoagulants, should be checked before departure.

- before departure.

  In clinical trials, the concomitant administration of sulfadoxine and pyrimethamine did not alter the adverse reaction profile of mefloquine.

  Carcinogenesis: Mutagenesis, Impairment of Fertility Carcinogenesis: The carcinogenic potential of mefloquine was studied in rats and mice in 2-year feeding studies at doses of up to 30 mg/kg/day. No treatment-related increases in tumors of any type were noted.

  Mutagenesis: The mutagenic potential of mefloquine was studied in a variety of assay systems including: Ames test, a host-mediated assay in mice, fluctuation tests and a mouse micronucleus assay. Several of these assays were performed with and without prior metabolic activation. In no instance was evidence obtained for the mutagenicity of mefloquine.

  Impairment of Fertility: Fertility studies in rats at doses of 5, 20, and 50 mg/kg/day of mefloquine have demonstrated adverse effects on fertility in the male at the high dose of 50 mg/kg/day, and in the femila at doses of 20 and 50 mg/kg/day, Histopathological lesions were noted in the epidicymides from male rats at doses of 20 and 50 mg/kg/day. Administration of 250 mg/kg/dexe, of mefloquine (base) in adult males for 22 weeks failed to reveal any deleterious effects on human spermatozoa.

  Pregnancy
- (base) in adult males for 22 weeks failed to reveal any deleterious effects on human spermatozoa. 
  Pregnancy Terratogenic Effects
  Pregnancy Category B
  Data from published studies in pregnant women have shown no increase in the risk of teratogenic effects or adverse pregnancy outcomes following mefloquine treatment or prophylaxis during regnancy. Reproduction studies in mice, rats and rabbits have shown teratogenic effects at doses similar to the clinical acute treatment dose in humans. Because the studies in humans cannot rule out the possibility of harm, mefloquine should be used during pregnancy only it clearly needed. 
  Published data on mefloquine use during pregnancy include randomized controlled trials, intervention trials, prospective and retrospective cohort studies, and case series. These data showed that pregnant women who took mefloquine at various doses for both prevention and treatment of malaria did not have an increased risk of teratogenic effects or adverse pregnancy outcomes compared to the background rate in the general population. These data include more than 700 exposures to mefloquine in the first trimester of pregnancy and over 2,000 exposures in the second and third trimester.

Mefloquine administered to pregnant mice, rats, and rabbits was teratogenic at doses similar to the clinical acute treatment dose of 21 to 25 mg/kg, based on body surface area comparisons. In all three animal species, CNS effects (e.g., exencephaly, hydrocephaly or partially missing medulia oblongata) and craniofacial malformations were observed. At the same doses, mefloquine was also embryotoxic in mice and rabbits. All of these findings were observed at doses that were maternally toxic.

Mursing Mothers

Mefloquine is excreted in human milk in small amounts, the activity of which is unknown. Based on a study in a few subjects, low concentrations (3% to 4%) of mefloquine were excreted in human milk following a dose equivalent to 250 mg of the free base. Caution should be exercised when administered to a nursing woman.

Administrator to a nusing worlan.

Pediatric Use

Use of mefloquine to treat acute, uncomplicated P. falciparum malaria in pediatric patients is supported by evidence from adequate and well-controlled studies of mefloquine in adults with additional data from published open-label and comparative trails using mefloquine to treat malaria caused by P. falciparum in patients younger than 16 years of age. The safety and effectiveness of mefloquine for the treatment of malaria in pediatric patients below the age of 6 months have not been established.

In several studies, the administration of mefloquine for the treatment of malaria was associated with early vomitting in pediatric patients. Early vomitting was cited in some reports as a possible cause of treatment failure. If a second dose is not tolerated, the patient should be monitored closely and alternative malaria treatment considered if improvement is not observed within a reasonable period of time (see WARNINGS and DOSAGE AND ADMINISTRATION).

Geriatric Use

Clinical studies of mefloquine did not include sufficient numbers of subjects aged 65 and older to determine whether they respond differently from younger subjects. Other reported clinical experience has not identified differences in responses between the elderly and younger patients. Since electrocardiographic abnormalities have been observed in individuals treated with mefloquine (see PREAUTIONS) and underlying cardiac disease is more prevalent in elderly than in younger patients, the benefits of mefloquine therapy should be weighed against the possibility of adverse cardiac effects in elderly patients. ADVERSE REACTIONS nical
the doses used for treatment of acute malaria infections, the symptoms possibly attributable
drug administration cannot be distinguished from those symptoms usually attributable to the
ease itself.

uisease itselii.
Among subjects who received mefloquine for prophylaxis of malaria, the most frequently observed adverse experience was vomitling (3%). Dizziness, syncope, extrasystoles and other complaints affecting less than 1% were also reported.

Two serious adverse reactions were cardiopulmonary arrest in one patient shortly after ingesting a single prophylactic dose of mefloquine while concomitantly using propranolol (see **PRECAUTIONS**, **Drug Interactions**), and encephalopathy of unknown etiology during prophylactic mefloquine administration. The relationship of encephalopathy to drug administration could not be clearly established.

Among subjects who received mefloquine for treatment, the most frequently observed adverse experiences included: dizziness, myalgia, nausea, fever, headache, vomiting, chills, diarrhea, skin rash, abdominal pain, fatigue, loss of appetite, and tinnitus. Those side effects occurring in less than 1% included bradycardia, hair loss, emotional problems, pruritus, asthenia, transient emotional disturbances and telogen effluvium (loss of resting hair). Seizures have also been reported.

disturbations and tengen sense.

Laboratory
The most frequently observed laboratory alterations which could be possibly attributable to drug administration were decreased hematocrit, transient elevation of transaminases, leukopenia and thrombocytopenia. These alterations were observed in patients with acute malaria who received treatment doses of the drug and were attributed to the disease itself. rearment doses of the oring and were attributed to the disease itself.

During prophylactic administration of mefloquine to indigenous populations in malaria-endemic areas, the following alterations in laboratory values were observed: transient elevation of transaminases, leukocytosis or thrombocytopenia.

Because of the long half-life of mefloquine, adverse reactions to mefloquine may occur or persist up to several weeks after discontinuation of the drug.

Postmarketing
Postmarketing
Postmarketing
Surveillance indicates that the same kind of adverse reactions are reported during
Postmarketing surveillance indicates that the same kind of adverse reactions are reported voluntarily
from a population of uncertain size, it is not always possible to reliably estimate their frequency or
establish a causal relationship to melfoquine exposure.

establish a causal relationiship to metroquine exposure.

The most frequently reported adverse reactions are nausea, vomiting, loose stools or diarri abdominal pain, dizziness or vertigo, loss of balance, and neuropsychiatric events such as headad somnoience, and sleep disorders (insomnia, abnormal dreams). These adverse reactions may or early in the course of mefloquine use. It has been reported that dizziness or vertigo, tinnitus hearing impairment, and loss of balance may continue for months or years after discontinuation the drug and may be permanent in some cases.

More severe neuropsychiatric disorders have been reported such as: sensory and motor neuropathies (including paresthesia, tremor and ataxia), convulsions, agitation or restlessness, anxiety, depression, mood swings, panic attacks, memory impairment, confusion, hallucinations, aggression, psychotic or paranoid reactions and encephalopathy. Cases of suicidal ideation and suicide have been reported. Other less frequently reported adverse reactions include:

Musculoskeletal Disorders: muscle weakness, muscle cramps, myalgia, and arthralgia. Respiratory Disorders: dyspnea, pneumonitis of possible allergic etiology. Hepatobiliary Disorders: drug-related hepatic disorders from asymptomatic transient transaminase elevations to hepatic failure. Blood and Lymphatic System Disorders: agranulocytosis, aplastic anemia

Cardiovascular Disorders: circulatory disturbances (hypotension, hypertension, flushing, syncope), chest pain, tachycardia or palpitation, bradycardia, irregular heart rate, extrasystoles, A-V block, and other transient cardiac conduction alterations. Skin Disorders: rash, exanthema, erythema, urticaria, pruritus, edema, hair loss, erythema multiforme, and Stevens-Johnson syndrome.

Other Symptoms: visual disturbances, asthenia, malaise, fatigue, fever, hyperhidrosis, chills, dyspepsia and loss of appetite. OVERDIOSAGE
Symptoms and Signs
In cases of overdosage with mefloquine, the symptoms mentioned under ADVERSE REACTIONS may be more pronounced. Treatment
Patients should be managed by symptomatic and supportive care following mefloquine overdc
There are no specific antidotes. Monitor cardiac function (if possible by ECG) and neuropsychia
status. Provide symptomatic and intensive supportive treatment as required.

DOSAGE AND DAMINISTRATION

Malaria Treatment in Adults

Treatment of mild to moderate malaria in adults caused by mefloquine-susceptible strains of P. falciparum or by P. vivax: Dosage: Five tablets (1250 mg) mefloquine hydrochloride to be given as a single oral dose. The drug should not be taken on an empty stomach and should be administered with at least 8 oz (240 mL) of water. If a full-treatment course with mefloquine does not lead to improvement within 48 to 72 hours, mefloquine should not be used for retreatment. An alternative therapy should be used. Similarly, it previous prophylaxis with mefloquine failed, mefloquine should not be used for curative treatment (see INDICATIONS AND USAGE). Note: Patients with acute *P. vivax* malaria, treated with mefloquine, are at high risk of relapse because mefloquine does not eliminate experythrocytic (hepatic phase) parasites. To avoid relapse after initial treatment of the acute infection with mefloquine, patients should subsequently be treated with an 8-aminoquinoline derivative (e.g., primaquine).

Malaria Prophylaxis in Adults Dosage: One 250 mg mefloquine hydrochloride ta Prophylactic drug administration should begin 1 w weekly doses should be taken regularly, always o main meal. To reduce the risk of malaria after lori for 4 additional weeks to ensure suppressive bloo the liver. Talbets should not be taken on an empty 8 oz (240 mL) of water. In certain cases, e.g., when a traveler is taking rophylaxis 2 to 3 weeks prior to departure, in orr	reek before arrival in an endemic area. Subsequen in the same day of each week, preferably after the ga en endemic area, prophylaxis must be continued I levels of the drug when merozoites emerge fron stomach and should be administered with at leas other medication, it may be desirable to star ler to ensure that the combination of drugs is wel
tolerated (see PRECAUTIONS, Drug Interactions). When prophylaxis with mefloquine fails, physicial use for therapy.  Malaria Treatment in Pediatric Patients Treatment of mild to moderate malaria in pediatric of P. falciparum: Dosage: 20 to 25 mg/kg body weig taken 6 to 8 hours apart may reduce the occurrent should not exceed the adult dose.  Experience with mefloquine in pediatric patients with the drug should not be taken on an empty stoma the tablets may be crushed and suspended in a sadministration to small children and other persons if a full-treatment course with mefloquine does mefloquine should not be used for retreatment. In pediatric patients, the administration of metasociated with early vomiting. In some cases, earreatment failure (see PRECAUTIONS). If a signific because of vomiting, a second full dose of mefloques than 30 minutes after receiving the drug. If vadditional half-dose should be given. If vomiting a daternative malaria treatment considered if it	ns should carefully evaluate which antimalarial to patients caused by mefloquine-susceptible strain. Int. Splitting the total therapeutic dose into 2 doses e or severity of adverse effects. The pediatric dose eighing less than 20 kg is limited. ch and should be administered with ample water small amount of water, milk or other beverage for unable to swallow them whole. not lead to improvement within 48 to 72 hours An alternative therapy should be used. Similarly ed, mefloquine should not be used for curative though the should be used for curative and to so if or up rought is observed or suspected and toss of frug product is observed or suspected and toss of frug product is observed or suspected and toss of frug product is observed or suspected into should be administered to patients who vominiting occurs 30 to 60 minutes after a dose, are dose, are dose, are dose, are dose, and the suspected of the suspected of the suspected or
and alternative malaria treatment considered if in period of time.  The safety and effectiveness of mefloquine to tre in months have not been established.  Malaria Prophylaxis in Pediatric Patients  The recommended prophylactic dose of mefloquine hydrochloride tablueghing over 45 kg. In pediatric patients weighin proportion to body weight:  30 to 45 kg: 3/4 tablet  20 to 30 kg: 1/2 tablet  Experience with mefloquine in pediatric patients weighting over 45 kg. In pediatric patients weighting proportion to body weight:	nat malaria in pediatric patients below the age of the same of the
Experience with memorphien in pleutant patients with MPM SUPPLIED Meffloquine Hydrochloride Tablets USP, 250 mg bevelet-edge, scored tablets, debossed with b 17 packaged in unit-dose cartons of 25 tablets. Store at 20° to 25°C (68° to 77°F) [See USP Cont KEEP THIS AND ALL MEDICATIONS OUT OF THE NAMIMAL TOXICOLOGY Coular lesions were observed in rats fed meflo 30 mg/kg/day had coular lesions in both eyes	are available as white, oval-shaped, flat-faced 1 on the scored side and plain on the other side rolled Room Temperature].  REACH OF CHILDREN.  quine daily for 2 years. All surviving rats giver
the lens, and retinal edema. Similar but less sev 22% of male rats fed 12.5 mg/kg/day for 2 years observed. They occurred in 9% of rats studied. Male Wistar rats orally administered-melloquine de Jasma concentration showed CNS penetration of drug ratio up to 10 days after the final dose admin REFERENCES. 1. Baudry S., Pham YT., Baune B., Vidrequin S. Stereoselective passage of melloquine through Pharmacol. 49: 1086-1090. TEVA PHARMAK Sellersville	ere lesions were observed in 80% of female and At doses of 5 mg/kg/day, only corneal lesions were all the second serious desions were used to serious design the serious design of the serious design
Medication Guide Mefloquine Hydrochloride Tablets USP Important: Four doctor or pharmacist will give you an Info Buide. It has important information about meflor while you take mefloquine. What is the most important information I should Mefloquine can cause serious side effects, inclu	Rev. B 6/2013  rmation Wallet Card along with this Medication quine and should be carried with you at all times  know about mefloquine?
1. Hearl Problems. Do not take halofantrine (used to treat malaria) mefloquine or within 15 weeks of your last dose problems with the electrical system of your hearbon ont take quinine (Qualaquin) or quinidine (umefloquine. You may get serious heart problems. S. Mental problems. Symptoms of serious menta severe anxiety  paranoia (feelings of mistrust towards others) hallucinations (seeing or hearing things that are depression feeling restless unusual behavior feeling confused Some people who take mefloquine think about si	f melfoquine. You may get serious heart problems rt called DT prolongation) that can lead to dead best of treat malaria or irregular heart beat) with I problems may include:  not there)
who were taking mefloquine committed suicide. Inhouse suicides.  If you have any of these serious mental problemental problems, you should contact your doctor mefloquine and use a different medicine to preven  3. Problems with your body's nervous system.  may include:  • dizziness  • a feeling that you or things around you are movi  • loss of balance	t is not known if mefloquine was responsible forms, or you develop other serious side effects or right away as it may be necessary to stop taking timalaria.  Symptoms of serious nervous system problems
<ul> <li>iniging sound in your ears (tinnitus)</li> <li>convulsions (seizures) in people who already ha</li> <li>convulsions (seizures) in people who take qui mefloquine. Do not take quinine (Qualaquin) or in unable to sleep (insomnia)</li> <li>Dizziness, vertigo, tinnitus, and loss of balance estopped or may become permanent in some peoimportant:</li> <li>You need to take malaria prevention medicine bi</li> </ul>	nine or chloroquine (used to treat malaria) with chloroquine (Aralen) with mefloquine. can go on for months or years after mefloquine is ple.
in a malaria area, and after you return from a m If you are told by a doctor to stop taking melloque you will need to take different malaria medicine. If you do not have access to a doctor or to anol leave the malaria area and contact a doctor as may not protect you from getting malaria. You for another 4 weeks after you leave the malaria: What is mefloquine? Melloquine is a prescription medicine used to fireatening infection. Melloquine does not work for tit is not known if mefloquine is safe and effective of malaria. It is not known how well mefloquine v han 44 pounds (20 kilograms). Who should not take mefloquine? Do not take mefloquine?	ine because of the side effects or for other reasons ther medicine and have to stop taking mefloquine soon as possible because leaving the malaria area will still need to take malaria prevention medicina area.  To revent and treat malaria. Malaria can be a life or all types of malaria.  In children under 6 months old for the treatmen
depression or had depression recently	isorder, schizophrenia, or psychosis (losing touch
<ul> <li>had recent mental problems, including anxiety d with reality)</li> <li>seizures or had seizures (epilepsy or convulsion</li> <li>an allergy to quinine, quinidine, mefloquine or a Medication Guide for a complete list of ingredier</li> <li>Medication Guide for a complete list of ingredier</li> <li>Medication Guide for before take mefloquine it y</li> <li>What should I tell my doctor before taking meflo Before taking mefloquine, tell your doctor aboreave:</li> </ul>	ny ingredients in mefloquine. See the end of this nts in mefloquine. bu have any of the medical conditions listed above quine?
<ul> <li>had recent mental problems, including anxiety d with reality)</li> <li>seizures or had seizures (epilepsy or convulsion</li> <li>an allergy to quinine, quinidine, mefloquine or a Medication Guide for a complete list of ingredier Talk to your doctor before you take mefloquine if yw What should I tell my doctor before taking meflo</li> <li>Before taking mefloquine, tell your doctor abor</li> </ul>	any ingredients in mefloquine. See the end of this tis in mefloquine. but have any of the medical conditions listed above quine?  It all your medical conditions, including if you decime (anticoagulants)  It known if mefloquine will harm your unborn baby to become pregnant.
had recent mental problems, including anxiety d with reality)     seizures or had seizures (epilepsy or convulsion     an allergy to quinine, quinidine, mefloquine or a Medication Guide for a complete list of ingredier latk to your doctor before you take mefloquine if y What should I tell my doctor before taking meflogence taking mefloquine, tell your doctor aborave:     heart disease     hier problems     seizures or epilepsy     diabetes     blood clotting problems or take blood thinner mental problems     are pregnant or plan to become pregnant. It is no Talk to your doctor if you are pregnant or plan to You should use birth control while you take mefloquine. If you have an unplanned pregnance are breastfeeding or plan to breastfeed. Mefloquyour baby. Ask your doctor if you will need to stonated your doctor about all the medicines, vitamins, and herbal supplements. No other causing side effects.  How should I take mefloquine?  Yake mefloquine exactly as your doctor tells yor.	any ingredients in mefloquine. See the end of this tis in mefloquine. Use the end of this tis in mefloquine. Use have any of the medical conditions listed above quine?  It all your medical conditions, including if you at all your medical conditions, including if you decicines (anticoagulants)  It known if mefloquine will harm your unborn baby a become pregnant.  It mefloquine and for 3 months after you stop y, talk to your doctor right away.  In medical medicine.  It after leaving a malaria area.  Lake, including prescription and nonprescription defloquine and other medicines may affect each out take it. Your doctor will tell you how many out to take it. Your doctor will tell you how many contents the seed of the contents are the contents and the contents are t
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• had recent mental problems, including anxiety of with reality)  • seizures or had seizures (epilepsy or convulsion an altergy to quinien, quindine, mefloquine or a Medication Guide for a compelle tist of ingredie Talk to your doctor before you take mefloquine if you Mhat should I tell my doctor before taking meflo Before taking mefloguine, tell your doctor about have:  • heart disease • liver problems • seizures or epilepsy • diabetes • liver problems • seizures or epilepsy • diabetes • liver problems or take blood thinner mental problems • nental problems • mental problems • mental problems • rare pregnant or plan to become pregnant. It is not Talk to your doctor if you are pregnant or plan to become pregnant. It is not Talk to your doctor if you are pregnant or plan to your aboy. Ask your doctor if you will need to stock to the plan to breastfeed. Mefloquyour baby. Ask your doctor if you will need to stock to the plan to breastfeed your baby. Ask your doctor you will need to stock to the plan to breastfeed my or beat to the plan to breastfeed my or beat to the plan to breastfeed. Mefloquyour baby. Ask your doctor to you will need to stock to the plan to breastfeed my or beat to take the plan to breastfeed my or beat to take the plan to breastfeed my or beat to take the plan to breastfeed my or beat to take the plan to the plan to breastfeed my or beat to take the plan to the plan to breastfeed my or beat to take the plan to the plan to breastfeed to the plan to the	any ingradients in mefloquine. See the end of this its in mefloquine.  but have any of the medical conditions listed above quine?  at all your medical conditions, including if you have any of the medical conditions, including if you decide the program.  It mefloquine will harm your unborn baby to become pregnant.  In mefloquine and for 3 months after you stop you lake to your dector right away.  In mefloquine and for 3 months after you stop you lake to your dector right away.  In can pass into your breast milk and may harm op breastfeeding or use a different medicine.  It are after leaving a malaria area.  It aske, including prescription and nonprescription leffloquine and other medicines may affect each aria between 1 to 3 weeks before you travel to a raria between 1 to 3 weeks before you travel to a raria between 1 to 3 weeks before you travel to a week lead of the day and with at least 1 cup (8 ounces for the property of the

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## **MEDICATION GUIDE**

Mefloquine Hydrochloride Tablets USF

Your doctor or pharmacist will give you an Information Wallet Card along with this after you return from a malaria area. Medication Guide. It has important information • If you are told by a doctor to stop taking about mefloquine and should be carried with you at all times while you take mefloquine.

What is the most important information I should know about mefloquine? Mefloquine can cause serious side effects, includina:

### 1. Heart Problems.

Do not take halofantrine (used to treat malaria) or ketoconazole (used for fungal infections) with mefloquine or within 15 weeks of your last dose of mefloquine. You may get serious heart problems (problems with the electrical system of your heart called QT prolongation) that can lead to death. Do not take guinine (Qualaguin) or quinidine (used to treat malaria or irregular heart beat) with mefloquine. You may get serious heart problems.

**2. Mental problems**. Symptoms of serious mental problems may include:

- severe anxiety
- paranoia (feelings of mistrust towards others) hallucinations (seeing or hearing things
- that are not there) denression
- feeling restless
- unusual behavior feeling confused

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.

If you have any of these serious mental problems, or you develop other serious side effects or mental problems, you should contact your doctor right away as it may be necessary to stop taking mefloquine and use a different medicine to prevent malaria.

3. Problems with your body's nervous system. Symptoms of serious nervous system problems may include:

- a feeling that you or things around you are seizures or epilepsy moving or spinning (vertigo)
- loss of balance
- ringing sound in your ears (tinnitus) convulsions (seizures) in people who
- already have seizures (epilepsy) convulsions (seizures) in people who take quinine or chloroquine (used to treat malaria) with mefloquine. Do not take quinine (Qualaquin) or chloroquine (Aralen) with mefloquine
- unable to sleep (insomnia)

Dizziness, vertigo, tinnitus, and loss of balance can go on for months or years after mefloquine is stopped or may become permanent in some people

## Important:

You need to take malaria prevention medicine before you travel to a malaria area, while you are in a malaria area, and

mefloquine because of the side effects or for other reasons, you will need to take different malaria medicine

If you do not have access to a doctor or to another medicine and have to stop taking mefloquine, leave the malaria area and contact a doctor as soon as possible because eaving the malaria area may not protect you from getting malaria. You will still need to take malaria prevention medicine for another 4 weeks after you leave the malaria area.

## What is mefloquine?

Mefloquine is a prescription medicine used to prevent and treat malaria. Malaria can be a life-threatening infection. Mefloquine does not work for all types of malaria.

It is not known if mefloquine is safe and effective in children under 6 months old for the treatment of malaria. It is not known how well mefloquine works to prevent malaria in children weighing less than 44 pounds (20 kilograms).

### Who should not take mefloquine? Do not take mefloquine if you have:

- depression or had depression recently had recent mental problems, including anxiety disorder, schizophrenia, or psychosis (losing touch with reality)
- seizures or had seizures (epilepsy or an allergy to guinine, guinidine, mefloguine or any ingredients in mefloquine. See the end of this Medication Guide for a

complete list of ingredients in mefloquine. Talk to your doctor before you take mefloquine if you have any of the medical conditions listed above.

What should I tell my doctor before taking mefloquine? Before taking mefloquine, tell your

doctor about all your medical conditions, including if you have:

- heart disease
- liver problems
- blood clotting problems or take blood thinner medicines (anticoagulants) mental problems
- are pregnant or plan to become pregnant. If is not known if mefloquine will harm your unborn baby. Talk to your doctor if you are pregnant or plan to become pregnant.
- You should use birth control while you take mefloquine and for 3 months after you **stop mefloquine.** If you have an unplanned pregnancy, talk to your doctor right away.

## **☆ MEDICATION GUIDE**

Mefloquine Hydrochloride Tablets USP Important:

Important:

You need to take malaria prevention

medicine before you travel to a malaria

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heart disease

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Do not take mefloquine if you have:

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Your doctor or pharmacist will give you a Information Wallet Card along with this after you return from a malaria area. **Medication Guide.** It has important information about mefloquine and should be carried with you at all times while you take mefloquine.

What is the most important information I should know about mefloquine? Mefloquine can cause serious side effects,

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2. Mental problems. Symptoms of serious mental problems may include: severe anxiety

- paranoia (feelings of mistrust towards others) hallucinations (seeing or hearing things
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- feeling restless unusual behavior

 feeling confused 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. If you have any of these serious mental problems, or you develop other serious side effects or mental problems, you should contact your doctor right away as it may be necessary to stop taking mefloquine and use a different medicine to prevent malaria.

3. Problems with your body's nervous system. Symptoms of serious nervous including if you have: system problems may include:

 dizziness • a feeling that you or things around you are • seizures or epilepsy moving or spinning (vertigo)

loss of balance

 diabetes blood clotting problems or take blood ringing sound in your ears (tinnitus) thinner medicines (anticoagulants)

t is important that you read the entire Medication Guide for additional information on mefloquine.

- convulsions (seizures) in people who already have seizures (epilepsy) convulsions (seizures) in people who take quinine or chloroquine (used to treat malaria) with mefloquine. Do not take quinine (Qualaquin) or chloroquine
- (Aralen) with mefloquine unable to sleep (insomnia)

Dizziness, vertigo, tinnitus, and loss of balance can go on for months or years after mefloquine is stopped or may become permanent in some people

Mefloquine Hydrochloride Tablets USP (mefloquine)

### $\times$ MEDICATION GUIDE

This label may not be the latest approved by FDA. For current labeling information, please visit https://www.fda.gov/drugsatfda

| Mefloquine Hydrochloride Tablets USP

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Mefloquine Hydrochloride Tablets USP (mefloquine)

unborn baby. Talk to your doctor if you are take quinine (Qualaquin) or chloroquine (Aralen) with mefloquine. unable to sleep (insomnia)

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nformation Wallet Card

You need to take malaria prevention medicine before you travel to a malaria area, while you are in a malaria area, and

- If you are told by a doctor to stop taking mefloquine because of the side effects or for other reasons, you will need to take different malaria medicine
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- depression or had depression recently had recent mental problems, including anxiety disorder, schizophrenia, or psychosis (losing touch with reality)
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- · heart disease
- liver problems
- blood clotting problems or take blood thinner medicines (anticoagulants)
- mental problems are pregnant or plan to become pregnant. It is not known if mefloquine will harm your unborn baby. Talk to your doctor if you are pregnant or plan to become pregnant.
- You should use birth control while you take mefloquine and for 3 months after you **stop mefloquine.** If you have an unplanned pregnancy, talk to your doctor right away.

## **Important**

**★ MEDICATION GUIDE** 

**Medication Guide.** It has important information

about mefloquine and should be carried with

What is the most important information I

Mefloquine can cause serious side effects,

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2. Mental problems. Symptoms of serious

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Some people who take mefloquine think about

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You should use birth control while you take

mefloquine and for 3 months after you

**stop mefloquine.** If you have an unplanned

pregnancy, talk to your doctor right away.

What should I tell my doctor before taking necessary to stop taking mefloquine and mefloauine? use a different medicine to prevent malaria. Before taking mefloquine, tell your 3. Problems with your body's nervous doctor about all your medical conditions, **system.** Symptoms of serious nervous including if you have: system problems may include:

- heart disease
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- convulsions (seizures) in people who mental problems already have seizures (epilepsy) are pregnant or plan to become pregnant. I convulsions (seizures) in people who is not known if mefloquine will harm your take quinine or chloroquine (used to unborn baby. Talk to your doctor if you are treat malaria) with mefloquine. Do not pregnant or plan to become pregnant
- unable to sleep (insomnia) Dizziness, vertigo, tinnitus, and loss of balance can go on for months or years after mefloquine is stopped or may become

Mefloquine Hydrochloride Tablets USP (mefloquine

Carry this wallet card with you when you are taking mefloquine.

take guinine (Qualaguin) or chloroguine

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permanent in some people.

Information Wallet Card

a malaria area.

Heart problems.

Important: Your doctor or pharmacist will give you an

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Mefloquine Hydrochloride Tablets USP

# Mefloquine can cause serious side effects, includina:

## 1. Heart Problems

**MEDICATION GUIDE** 

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loss of balance

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Information Wallet Card

mefloquine is stopped or may become

Mefloquine Hydrochloride Tablets USP (mefloquine

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  - pregnant or plan to become pregnant. You should use birth control while you take mefloquine and for 3 months after you
  - stop mefloquine. If you have an unplanned pregnancy, talk to your doctor right away.

# Mefloguine Hydrochloride Tablets USP (mefloguine)

It is important that you read the entire Medication Guide for additional information on mefloquine Carry this wallet card with you when you are taking mefloquine Important: You need to take malaria prevention taking mefloquine committed suicide. It is not known

# you are in a malaria area, and after you return from If you have any of these serious mental proble

or ketoconazole (used for fungal infections) with **l Do not** take quinine (Qualaquin) or chloroquir nefloquine. You may get serious heart problems that I may have a greater risk for convulsions (seizures). an lead to death. **Do not** take quinine (Qualaquin) | Symptoms of serious nervous system problems may or quinidine (used to treat malaria or irregular heart include dizziness, a feeling that you or things around beat) with mefloquine. You may get serious heart problems. Mefloquine may cause serious problems with the electrical system of your heart, called QT in people who already have seizures, or you are unable

2. Mental problems. Symptoms of serious mental | These serious mental and nervous system side hearing things that are not there), depression, in some people rearing things that are not deleng confused. Some people who take mefloquine think about suicide (putting an end to their life). Some people who were who take mefloquine think about suicide (putting an end to their life). Some people who were

### medicine before you travel to a malaria area, while | mefloquine was responsible for those suicides. you should contact your doctor right away as it may Mefloquine can cause serious side effects, including: be necessary to stop taking mefloquine and use a different medicine to prevent malaria. Do not take halofantrine (used to treat malaria) 3. Problems with your body's nervous system.

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to sleep (insomnia). roblems may include severe anxiety, paranoia (feelings effects can go on for months or years after mistrust towards others), hallucinations (seeing mefloquine is stopped or may become permanent

earing things that are not there), depression, in some people

Carry this wallet card with you when you are taking mefloquine. Important: You need to take malaria prevention taking mefloquine committed suicide. It is not known medicine before you travel to a malaria area, while mefloquine was responsible for those suicides. a malaria area

. Heart problems.

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you are in a malaria area, and after you return from I If you have any of these serious mental prob you should contact your doctor right away as it may Mefloquine can cause serious side effects, including: be necessary to stop taking mefloquine and use different medicine to prevent malaria. Do not take halofantrine (used to treat malaria) 3. Problems with your body's nervous system. r ketoconazole (used for fungal infections) with **loo not** take quinine (Qualaquin) or chlorogu

in lead to death. **Do not** take quinine (Qualaquin) Symptoms of serious nervous system problems ma quinidine (used to treat malaria or irregular heart include dizziness, a feeling that you or things around at) with mefloquine. You may get serious heart you are moving or spinning (vertigo), loss of balance, with the electrical system of your heart, called QT in people who already have seizures, or you are unable to sleep (insomnia) . Mental problems. Symptoms of serious mental | These serious mental and nervous system side ems may include severe anxiety, paranoia (feelings | effects can go on for months or years after mistrust towards others), hallucinations (seeing mefloquine is stopped or may become permanent

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relating timings that are not therefore, depression, seling restless, unusual behavior or feeling confused.

If you are told by a doctor to stop taking mefloquine because of the side effects or for other reasons, you will need to take a different malaria medicine. me people who take mefloquine think about suicide utting an end to their life). Some people who were will need to take a different malaria medicine.

Carry this wallet card with you when you are taking mefloquine medicine before you travel to a malaria area, while medicine was responsible for those suicides

# different medicine to prevent malaria.

is important that you read the entire Medication Guide for additional information on mefloquine.

Mefloquine can cause serious side effects, including: be necessary to stop taking mefloquine and use

ketoconazole (used for fungal infections) with **| Do not** take quinine (Qualaquin) or chlorog quine or within 15 weeks of your last dose of (Aralen) (used to treat malaria) with mefloo efloquine. You may get serious heart problems that I may have a greater risk for convulsions (seizures). n lead to death. **Do not** take quinine (Qualaquin) | Symptoms of serious nervous system problems ma r quinidine (used to treat malaria or irregular heart include dizziness, a feeling that you or things around with mefloquine. You may gause serious problems. Mefloquine may cause serious problems ringing in your ears (tinnitus), convulsions (seizures) with the electrical system of your heart, called QT | in people who already have seizures, or you are unable 2. Mental problems. Symptoms of serious mental These serious mental and nervous system sid

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blems may include severe anxiety, paranoia (feelings) effects can go on for months or years after mistrust towards others), hallucinations (seeing mefloquine is stopped or may become permanen ion, **in some people.** eling restless, unusual behavior or feeling confused. If you are told by a doctor to stop taking mefloquing

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Mefloquine can cause serious side effects, including: be necessary to stop taking mefloquine and use

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different medicine to prevent malaria. Do not take halofantrine (used to treat malaria) 3. Problems with your body's nervous system. ketoconazole (used for fungal infections) with **Do not** take quinine (Qualaquin) or chlorog

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Mental problems. Symptoms of serious mental These serious mental and nervous system si ns may include severe anxiety, paranoia (feelings effects can go on for months or years after mistrust towards others), hallucinations (seeing mefloquine is stopped or may become permaner <sup>1,</sup> I in some neonle.

la malaria area.

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Do not take halofantrine (used to treat malaria) 3. Problems with your body's nervous system.

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?. Mental problems. Symptoms of serious mental | These serious mental and nervous system s

feeling restless, unusual behavior or feeling confused. Some people who take mefloquine think about suicide (putting an end to their life). Some people who were

# medicine before you travel to a malaria area, while you are in a malaria area, and

You need to take malaria prevention

Information Wallet Card along with this after you return from a malaria area. Medication Guide. It has important information • If you are told by a doctor to stop taking mefloquine because of the side effects or for other reasons, you will need to take

different malaria medicine

 If you do not have access to a doctor or to another medicine and have to stop taking mefloquine, leave the malaria area and contact a doctor as soon as possible because eaving the malaria area may not protect you from getting malaria. You will still need to take malaria prevention medicine for another 4 weeks after you leave the malaria area.

# What is mefloquine?

Important:

Mefloquine is a prescription medicine used to prevent and treat malaria. Malaria can be a life-threatening infection. Mefloquine does not work for all types of malaria. It is not known if mefloquine is safe and

effective in children under 6 months old for the treatment of malaria. It is not known how well mefloquine works to prevent malaria in children weighing less than 44 pounds (20 kilograms) Who should not take mefloquine? Do not take mefloquine if you have:

· depression or had depression recently

had recent mental problems, including

anxiety disorder, schizophrenia, or

psychosis (losing touch with reality) seizures or had seizures (epilepsy or convulsions) an allergy to quinine, quinidine, mefloquine

the end of this Medication Guide for a complete list of ingredients in mefloquine. Talk to your doctor before you take mefloquine if you have any of the medical

What should I tell my doctor before taking Before taking mefloguine, tell your

conditions listed above.

• blood clotting problems or take blood ringing sound in your ears (tinnitus)

is not known if mefloquine will harm you take quinine or chloroquine (used to unborn baby. Talk to your doctor if you are treat malaria) with mefloquine. Do not

take quinine (Qualaguin) or chloroguine Dizziness, vertigo, tinnitus, and loss of balance can go on for months or years after

t is important that you read the entire Medication Guide for additional information on mefloquine Carry this wallet card with you when you are taking mefloquine.

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### • are breastfeeding or plan to breastfeed. Call your healthcare provider right away if you on the are breastfeeding or plan to breastfeed. Call your healthcare provider right away if you on the are breastfeeding or plan to breastfeed. Call your healthcare provider right away if you on the are breastfeeding or plan to br Mefloquine can pass into your breast milk have unexplained symptoms such as nausea and may harm your baby. Ask your doctor or vomiting, stomach pain, fever, weakness, if you will need to stop breastfeeding or itching, unusual tiredness, loss of appetite, light use a different medicine

# a fever after leaving a malaria area.

Tell your doctor about all the medicines you include: take, including prescription and nonprescription • nausea medicines, vitamins, and herbal supplements. • vomiting Mefloquine and other medicines may affect • diarrhea each other causing side effects.

## How should I take mefloquine?

- Take mefloquine exactly as your doctor The most common side effects in people tells you to take it. Your doctor will tell you who take mefloquine for treatment include: how many mefloquine tablets to take and • muscle pain when to take them.
- chills You will start taking mefloquine to prevent skin rash malaria between 1 to 3 weeks before you fatique travel to a malaria area.
- Take mefloquine just after eating your loss of appetite largest meal of the day and with at least • irregular heart beat 1 cup (8 ounces) of water.
- Do not take mefloquine on an empty stomach
- If you vomit after taking mefloquine. contact your doctor to see if you should doctor or pharmacist. take another dose
- Continue taking mefloquine for 4 weeks side effects. You may report side effects to after returning from a malaria area.
- Mefloquine tablets may be crushed and How should I store mefloquine? mixed with a small amount of water, milk or • Store mefloquine between 20°C to 25°C other beverage for children or other people (68°F to 77°F) unable to swallow mefloquine whole. Your • Safely throw away medicine that is out of doctor will tell you the correct dose for your date or no longer needed. child based on your child's weight
- If you take mefloquine for a year or longer, the reach of children. vour doctor should check your: • eves (especially if you have trouble
- seeing while you take mefloquine) liver function (to see if there has been damage to your liver)
- Use protective clothing, insect repellents, and bed nets to protect you from being a condition for which it was not prescribed. bitten by mosquitoes. Medicine alone does not always stop you from catching even if they have the same symptoms that malaria from mosquito bites.

# What should I avoid while taking

Avoid activities such as driving a car or using you would like more information, talk with heavy machinery or other activities needing your doctor. You can ask your pharmacist alertness and careful movements (fine motor or doctor for information about mefloquine coordination) until you know how mefloquine that is written for health professionals. affects you. You may feel dizzy or lose your What are the ingredients in mefloquine balance. This could happen for months or hydrochloride tablets USP? years after you stop taking mefloquine and Active ingredient: mefloquine hydrochloride can be permanent in some cases. See "What Inactive ingredients: colloidal silicon dioxide, | are the possible side effects of mefloquine?" corn starch, crospovidone, lactose monohydrate, What are the possible side effects of magnesium stearate, microcrystalline cellulose,

### mefloquine? See "What is the most important information This Medication Guide has been approved I should know about mefloquine?"

Mefloquine may cause serious side effects, including: liver problems

vou leave the malaria area.

colored bowel movements, dark colored urine. Contact your doctor right away if you have yellowing of your skin or the white of your eyes. Contact your doctor right away if you have yellowing of your skin or the white of your eyes.

that bothers you or that does not go away.

These are not all the possible side effects of

mefloquine. For more information, ask your

Call vour doctor for medical advice about

Keep mefloquine and all medicines out of

General information about the safe and

Medicines are sometimes prescribed

for purposes other than those listed in a

Medication Guide. Do not use mefloquine for

Do not give mefloquine to other people,

important information about mefloquine. If

FDA at 1-800-FDA-1088.

effective use of mefloquine.

you have. It may harm them.

abdominal pain

headache

# The most common side effects of mefloquine a fever after leaving a malaria area.

# How should I take mefloquine?

- tells you to take it. Your doctor will tell you who take mefloquine for treatment include: how many mefloquine tablets to take and when to take them.
- malaria between 1 to 3 weeks before you travel to a malaria area. Take mefloquine just after eating your
- Tell your doctor if you have any side effect 1 cup (8 ounces) of water. Do not take mefloquine on an empty
  - If you yomit after taking mefloquine contact your doctor to see if you should doctor or pharmacist. take another dose
  - Continue taking mefloquine for 4 weeks side effects. You may report side effects to after returning from a malaria area.
  - Mefloquine tablets may be crushed and How should I store mefloquine? mixed with a small amount of water, milk or • Store mefloquine between 20°C to 25°C other beverage for children or other people (68°F to 77°F) unable to swallow mefloquine whole. Your • Safely throw away medicine that is out of doctor will tell you the correct dose for your date or no longer needed. child based on your child's weight
  - your doctor should check your.
  - damage to your liver)
  - malaria from mosquito bites.

# mefloquine? Avoid activities such as driving a car or using you would like more information, talk with

can be permanent in some cases. See "What Inactive ingredients: colloidal silicon dioxide, are the possible side effects of mefloquine?" corn starch, crospovidone, lactose monohydrate, What are the possible side effects of magnesium stearate, microcrystalline cellulose,

### pregelatinized starch, poloxamer and talc. mefloquine? I should know about mefloquine?" by the U.S. Food and Drug Administration. TEVA PHARMACEUTICALS USA

effects, including

u leave the malaria area.

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If you do not have access to a doctor or to a different Tell your doctor if you have any side effect that medicine and have to stop taking mefloquine, leave the malaria area and contact a doctor as soon as possible all the possible side effects of mefloquine. For more because leaving the malaria area may not protect information, ask your doctor or pharmacist. you from getting malaria. You will still need to take a Call your doctor for medical advice about side effects.

## llaria prevention medicine for another 4 weeks after You may report side effects to FDA at 1-800-FDA-1088. What should I avoid while taking mefloquine?

Sellersville, PA 18960

oquine may cause serious liver problems. Avoid activities such as driving a car or using heavy Mefloquine may cause serious **IIVER PROBLEMS.**Symptoms of liver problems include nausea, vomiting, loss of appetite, unusual tiredness, stomach pain, fever, weakness, itching, light-colored bowel movements, dark colored urine, yellowing of your skin or the white of your eyes. The most **common side effects** of mefloquine include nausea, vomiting, diarrhea, abdominal pain and headache.

Avoid activities such as driving a car or using neavy machinery or other activities needing alertness and careful movements (fine motor coordination) 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.

Mefloquine can pass into your breast milk have unexplained symptoms such as nausea and may harm your baby. Ask your doctor or vomiting, stomach pain, fever, weakness, if you will need to stop breastfeeding or itching, unusual tiredness, loss of appetite, light use a different medicine.

Tell your doctor about all the medicines you include take, including prescription and nonprescription • nausea medicines, vitamins, and herbal supplements. • vomiting Mefloquine and other medicines may affect • diarrhea each other causing side effects.

## headache Take mefloquine exactly as your doctor The most common side effects in people muscle pain

- You will start taking mefloquine to prevent
- largest meal of the day and with at least
- stomach

- Keep mefloquine and all medicines out of If you take mefloquine for a year or longer, the reach of children. General information about the safe and eves (especially if you have trouble effective use of mefloquine.
- seeing while you take mefloquine) • liver function (to see if there has been
- Use protective clothing, insect repellents, and bed nets to protect you from being a condition for which it was not prescribed. bitten by mosquitoes. Medicine alone does not always stop you from catching This Medication Guide summarizes the most | What should I avoid while taking

heavy machinery or other activities needing your doctor. You can ask your pharmacist alertness and careful movements (fine motor or doctor for information about mefloquine coordination) until you know how mefloquine that is written for health professionals. affects you. You may feel dizzy or lose your What are the ingredients in mefloquine balance. This could happen for months or hydrochloride tablets USP? years after you stop taking mefloquine and Active ingredient: mefloquine hydrochloride

See "What is the most important information This Medication Guide has been approved Mefloquine may cause serious side

liver problems

f you do not have access to a doctor or to a different | Tell your doctor if you have any side effect that nedicine and have to stop taking mefloquine, leave the halaria area and contact a doctor as soon as possible all the possible side effects of mefloquine. For more cause leaving the malaria area may not protect information, ask your doctor or pharmacist. ou from getting malaria. You will still need to take a Call your doctor for medical advice about side effects.

# alaria prevention medicine for another 4 weeks after You may report side effects to FDA at 1-800-FDA-1088. mptoms of liver problems include nausea, vomiting, is of appetite, unusual tiredness, stomach pain, fever,

What should I avoid while taking mefloquine? oquine may cause serious liver problems. Avoid activities such as driving a car or using heavy machinery or other activities needing alertness and oss of appetite, unusual uredniess, sumach pain, revel, weakness, itching, light-colored bowel movements, dark colored urine, yellowing of your skin or the white of your eyes. The most **common side effects** of mefloquine include nausea, vomiting, diarrhea, belowing the permanent in some cases.

colored bowel movements, dark colored urine.

The most common side effects of mefloquine

Tell your doctor if you have any side effect

that bothers you or that does not go away.

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Medicines are sometimes prescribed

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Do not give mefloquine to other people,

even if they have the same symptoms that

This Medication Guide summarizes the most

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pregelatinized starch, poloxamer and talc.

by the U.S. Food and Drug Administration.

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Sellersville PA 18960

you have. It may harm them.

abdominal pain

chills

fatique

skin rash

loss of appetite

• irregular heart beat

FDA at 1-800-FDA-1088.

ou leave the malaria area.

ledicine and have to stop taking mefloquine, leave the bothers you or that does not go away. These are not lalaria area and contact a doctor as soon as possible all the possible side effects of mefloquine. For more ecause leaving the malaria area may not protect information, ask your doctor or pharmacist. ou from getting malaria. You will still need to take a Call your doctor for medical advice about side effects.

pregelatinized starch, poloxamer and talc.

# What should I avoid while taking mefloguine?

ymptoms of liver problems include nausea, vomiting, so of appetite, unusual tiredness, stomach pain, fever, as of appetite, unusual tiredness, stomach pain, fever, activities needing alertness and careful may man (fine matter coordination) until your configuration) until your configuration of the coordination of the coordina loss of appetite, unusual tiredness, stomach pain, fever, weakness, itching, light-colored bowel movements, dark colored urine, yellowing of your skin or the white of your eyes. The most **common side effects** of mefloquine include nausea, vomiting, diarrhea, and of medical pain and headache. Mefloquine can pass into your breast milk have unexplained symptoms such as nausea and may harm your baby. Ask your doctor or vomiting, stomach pain, fever, weakness, if you will need to stop breastfeeding or itching, unusual tiredness, loss of appetite, light use a different medicine. colored bowel movements, dark colored urine.

### Contact your doctor right away if you have yellowing of your skin or the white of your eyes. a fever after leaving a malaria area.

Tell your doctor about all the medicines you include: take, including prescription and nonprescription • nausea medicines, vitamins, and herbal supplements. Mefloquine and other medicines may affect • diarrhea each other causing side effects.

- How should I take mefloquine? The most common side effects in people Take mefloquine exactly as your doctor tells you to take it. Your doctor will tell you who take mefloquine for treatment include: muscle pain how many mefloquine tablets to take and when to take them. chills You will start taking mefloquine to prevent
- malaria between 1 to 3 weeks before you travel to a malaria area. • Take mefloquine just after eating your largest meal of the day and with at least • irregular heart beat
- 1 cup (8 ounces) of water. • Do not take mefloquine on an empty stomach
- mefloquine. For more information, ask your If you vomit after taking mefloquine. contact your doctor to see if you should doctor or pharmacist. Call your doctor for medical advice about take another dose
- Continue taking mefloquine for 4 weeks side effects. You may report side effects to after returning from a malaria area. Mefloquine tablets may be crushed and How should I store mefloquine?
- mixed with a small amount of water, milk or Store mefloquine between 20°C to 25°C other beverage for children or other people (68°F to 77°F) unable to swallow mefloquine whole. Your • Safely throw away medicine that is out of doctor will tell you the correct dose for your date or no longer needed. child based on your child's weight Keep mefloquine and all medicines out o
- If you take mefloquine for a year or longer, the reach of children. your doctor should check your.
- eves (especially if you have trouble effective use of mefloquine. seeing while you take mefloguine) liver function (to see if there has been damage to your liver)
- Use protective clothing, insect repellents. and bed nets to protect you from being bitten by mosquitoes. Medicine alone does not always stop you from catching malaria from mosquito bites. What should I avoid while taking

# mefloquine?

Avoid activities such as driving a car or using you would like more information, talk with heavy machinery or other activities needing your doctor. You can ask your pharmacist alertness and careful movements (fine motor or doctor for information about mefloquine coordination) until you know how mefloquine that is written for health professionals. affects you. You may feel dizzy or lose your What are the ingredients in mefloquine balance. This could happen for months or hydrochloride tablets USP? years after you stop taking mefloquine and Active ingredient: mefloquine hydrochloride mefloquine?

I should know about mefloquine?"

Mefloquine may cause serious side effects, including: liver problems

If you do not have access to a doctor or to a different | Tell your doctor if you have any side effect that edicine and have to stop taking mefloquine, leave the bothers you or that does not go away. These are not alaria area and contact a doctor as soon as possible all the possible side effects of mefloquine. For more

cause leaving the malaria area may not protect information, ask your doctor or pharmacist. u from getting malaria. You will still need to take a Call your doctor for medical advice about side effects.

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- child based on your child's weight If you take mefloquine for a year or longer, the reach of children. your doctor should check your. General information about the safe and
  - eyes (especially if you have trouble effective use of mefloquine seeing while you take mefloguine) liver function (to see if there has been damage to your liver)
  - Use protective clothing, insect repellents. bitten by mosquitoes. Medicine alone malaria from mosquito bites. What should I avoid while taking

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Mefloquine may cause serious side effects, including: liver problems

Mefloquine can pass into your breast milk have unexplained symptoms such as nausea and may harm your baby. Ask your doctor or vomiting, stomach pain, fever, weakness, if you will need to stop breastfeeding or itching, unusual tiredness, loss of appetite, light colored bowel movements, dark colored urine,

Contact your doctor right away if you have yellowing of your skin or the white of your eyes. The most common side effects of mefloquine

- abdominal pain
- headache
- Take mefloquine exactly as your doctor The most common side effects in people
  - muscle pain

  - skin rash fatique
  - loss of appetite
  - that bothers you or that does not go away. These are not all the possible side effects of mefloquine. For more information, ask your

Call your doctor for medical advice about • Continue taking mefloquine for 4 weeks side effects. You may report side effects to FDA at 1-800-FDA-1088.

- mixed with a small amount of water, milk or Store mefloquine between 20°C to 25°C
- doctor will tell you the correct dose for your date or no longer needed. Keep mefloquine and all medicines out of

# General information about the safe and

Medicines are sometimes prescribed for purposes other than those listed in a Medication Guide. Do not use mefloquine for

Do not give mefloquine to other people does not always stop you from catching even if they have the same symptoms that This Medication Guide summarizes the most important information about mefloquine. If

# affects you. You may feel dizzy or lose your What are the ingredients in mefloquine

years after you stop taking mefloquine and Active ingredient: mefloquine hydrochloride can be permanent in some cases. See "What Inactive ingredients: colloidal silicon dioxide, are the possible side effects of mefloquine?" corn starch, crospovidone, lactose monohydrate What are the possible side effects of magnesium stearate, microcrystalline cellulose, pregelatinized starch, poloxamer and talc.

See "What is the most important information This Medication Guide has been approved by the U.S. Food and Drug Administration.

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Mefloquine may cause serious side effects, including liver problems

I should know about mefloquine?"

heavy machinery or other activities needing your doctor. You can ask your pharmacist alertness and careful movements (fine motor or doctor for information about mefloquine coordination) until you know how mefloquine that is written for health professionals. affects you. You may feel dizzy or lose your What are the ingredients in mefloquine balance. This could happen for months or **hydrochloride tablets USP?** years after you stop taking mefloquine and Active ingredient: mefloquine hydrochloride

laria prevention medicine for another 4 weeks after You may report side effects to FDA at 1-800-FDA-1088. offoquine may cause serious liver problems. Avoid activities such as driving a car or using heav

ninal nain and headache TEVA PHARMACEUTICALS USA

by the U.S. Food and Drug Administration. TEVA PHARMACEUTICALS USA Sellersville, PA 18960 Rev. B 6/2013 If you do not have access to a doctor or to a different Tell your doctor if you have any side effect that

does not always stop you from catching even if they have the same symptoms that you have. It may harm them. This Medication Guide summarizes the most important information about mefloquine. If Avoid activities such as driving a car or using You would like more information, talk with

This label may not be the latest approved by FDA. For current labeling information, please visit https://www.fda.gov/drugsatfda

colored bowel movements, dark colored urine.

The most common side effects of mefloquine

Tell your doctor if you have any side effect

that bothers you or that does not go away.

These are not all the possible side effects of

mefloquine. For more information, ask your

Call your doctor for medical advice about

Keep mefloquine and all medicines out of

General information about the safe and

Medicines are sometimes prescribed

for purposes other than those listed in a

Medication Guide. Do not use mefloquine for

Do not give mefloquine to other people,

Mefloquine can pass into your breast milk have unexplained symptoms such as nausea

and may harm your baby. Ask your doctor or vomiting, stomach pain, fever, weakness,

if you will need to stop breastfeeding or itching, unusual tiredness, loss of appetite, light

abdominal pain

headache

fever

chills

fatique

skin rash

loss of appetite

FDA at 1-800-FDA-1088

Contact your doctor right away if you have yellowing of your skin or the white of your eyes.

• Take mefloquine exactly as your doctor The most common side effects in people

tells you to take it. Your doctor will tell you who take mefloquine for treatment include:

Continue taking mefloquine for 4 weeks side effects. You may report side effects to

mixed with a small amount of water, milk or • Store mefloquine between 20°C to 25°C

unable to swallow mefloquine whole. Your • Safely throw away medicine that is out of

and bed nets to protect you from being a condition for which it was not prescribed.

can be permanent in some cases. See "What Inactive ingredients: colloidal silicon dioxide,

are the possible side effects of mefloquine?" corn starch, crospovidone, lactose monohydrate,

What are the possible side effects of magnesium stearate, microcrystalline cellulose,

See "What is the most important information This Medication Guide has been approved

• Mefloquine tablets may be crushed and How should I store mefloquine?

doctor will tell you the correct dose for your date or no longer needed.

• eyes (especially if you have trouble effective use of mefloquine

If you take mefloquine for a year or longer, the reach of children.

use a different medicine.

each other causing side effects.

when to take them.

stomach

take another dose

travel to a malaria area.

1 cup (8 ounces) of water.

How should I take mefloquine?

You will start taking mefloquine to prevent

Take mefloquine just after eating your

Do not take mefloquine on an empty

• If you yomit after taking mefloquine

after returning from a malaria area.

child based on your child's weight

vour doctor should check your.

damage to your liver)

malaria from mosquito bites.

mefloquine?

mefloquine?

seeing while you take mefloquine)

Use protective clothing, insect repellents,

| What should I avoid while taking

• liver function (to see if there has been

bitten by mosquitoes. Medicine alone

malaria between 1 to 3 weeks before you

a fever after leaving a malaria area.

Tell your doctor about all the medicines you include:

take, including prescription and nonprescription • nausea

medicines, vitamins, and herbal supplements. • vomiting

how many mefloquine tablets to take and • muscle pain

largest meal of the day and with at least irregular heart beat

contact your doctor to see if you should doctor or pharmacist.

other beverage for children or other people (68°F to 77°F)

Mefloquine and other medicines may affect • diarrhea

Medication Guide. Do not use mefloquine for a condition for which it was not prescribed.

u leave the malaria area. s of appetite, unusual tiredness, stomach pain, fever,

alaria prevention medicine for another 4 weeks after You may report side effects to FDA at 1-800-FDA-1088. What should I avoid while taking mefloquine? offoquine may cause serious liver problems. Avoid activities such as driving a car or using heav nptoms of liver problems include nausea, vomiting, machinery or other activities needing alertness and cness, itching, light-colored bowel movements, know how mefloquine affects you. You may feel dizzy dark colored urine, yellowing of your skin or the white of your eyes. The most **common side effects** of mefloquine include nausea, vomiting, diarrhea, the state are and beadeaba. When the state are the state are

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Do not give mefloquine to other people, even if they have the same symptoms that you have. It may harm them. This Medication Guide summarizes the most important information about mefloquine. If

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The most common side effects of mefloquine

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abdominal pain

headache

skin rash

· loss of appetite

FDA at 1-800-FDA-1088.

fatique

can be permanent in some cases. See "What Inactive ingredients: colloidal silicon dioxide, are the possible side effects of mefloquine?" corn starch, crospovidone, lactose monohydrate, What are the possible side effects of magnesium stearate, microcrystalline cellulose, pregelatinized starch, poloxamer and talc. See "What is the most important information This Medication Guide has been approved by the U.S. Food and Drug Administration

If you do not have access to a doctor or to a different Tell your doctor if you have any side effect that

you from getting malaria. You will still need to take a Call your doctor for medical advice about side effects nalaria prevention medicine for another 4 weeks after You may report side effects to FDA at 1-800-FDA-1088. you leave the malaria area. Mefloquine may cause serious liver problems. Avoid activities such as driving a car or using heav

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Tell your doctor if you have any side effect

• Mefloquine tablets may be crushed and How should I store mefloquine?

and bed nets to protect you from being a condition for which it was not prescribed. you have. It may harm them.