

Mefloquine may cause neuropsychiatric adverse reactions that can persist after mefloquine has been discontinued.

Melloquine should not be prescribed for prophylaxis in patients with major psychiatric disorders. During prophylactic use, if psychiatric or neurologic symptoms occur, the drug should be discontinued and an alternative medication should be substituted (see WARNINGS).

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magnesium stearate, microcrystalline cellulose, pregelatinized starch, poloxamer and talc.

CLINICAL PHARMACOLOGY

Pharmacokinestics

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, plasmoconcentrations 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 mcg/L are roughly equivalent to the dose in milligrams (for example, a single 1000 mg dose produces a maximum concentration of about 1000 mcg/L). In healthy volunteers, a dose of 250 mg once weekly produces maximum steady-state plasma concentrations of 1000 to 2000 mcg/L, which are reached after 7 to 10 weeks.

Distribution: In healthy adults, the apparent volume of distribution is approximately 20 L/kg, indicating extensive tissue distribution. Mefloquine may accumulate in parastitzed erythrocytes. Experiments conducted in virtue with human blood using concentrations between 50 and 1000 mg/mL showed a relatively constant erythrocyte-to-plasma concentration ratio of about 2 to 1. The equilibrium reached in less than 30 minutes was found to be reversible. Protein binding is about 98%.

Mefloquine crosses the placenta. Excretion into breast milk appears to be minimal (see PRECAUTIONS,

In which all in why studies strongly suggested that CTF3444 is the implain bedomit movied. Two metabolities of mefloquine have been identified in humans. The main metabolite, 2.8-bis-trifluoromethyl-4-quinoline carboxylic acid, is inactive in Plasmodium falciparum. 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 mefloquine, were reached after 2 weeks. Thereafter, plasma levels of the main metabolite and mefloquine 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. Interior, was present in initiude quantities only. Illimination: 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 lepatic, is in the order of 30 mL/min. There is evidence that mefloquine is excreted mainly in the ind feces. In volunteers, urinary excretion of unchanged mefloquine and its main metabolite under teady-state condition accounted for about 9% and 4% of the dose, respectively. Concentrations of ther metabolites could not be measured in the urine.

Pharmacokinetics in Special Clinical Situations: Children and the Elderly. No relevant age-related changes have been observed in the pharmacokinetics of melloquine. Therefore, the dosage for children has been extrapolated from the recommended adult dose.

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 hemodialysis. No special chemoprophylactic dosage adjustments 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 has no clinically relevant effect on the pharmacokinetics of mefloquine.

ethnic populations.

The pharmacokinetics of mefloquine may be altered in acute malaria.

During long-term prophylaxis (>2 years), the trough concentrations and the elimination half-life of mefloquine were similar to those obtained in the same population after 6 months of drug use, which is when they reached steady-state. In vitro and in vivo studies showed no hemolysis associated with glucose-6-phosphate dehydrogenase 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.

hetween metloquine and quinine have been observed in some regions.

IMDICATIONS AND USAGE

Treatment of Acute Malaria Infections

Metloquine Hydrochloride Tablets USP are indicated for the treatment of mild to moderate acute
malaria caused by metloquine-susceptible strains of P. falciparum (both chloroquine-susceptible and
resistant strains) or by Plasmodium vivax. There are insufficient clinical data to document the effect
of metloquine in malaria caused by P. ovale or P. malariae.

Note: Patients with acute P. vivax malaria, treated with metloquine, are at high risk of relapse because
metloquine does not eliminate excerythrocytic (hepatic phase) parasites. To avoir elapse, after initial
treatment of the acute infection with metloquine, patients should subsequently be treated with an
8-aminoquinoline derivative (e.g., primaquine).

Prevention of Malaria Prevention of Mataria 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*. 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 rotaletd 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.

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

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Psychiatric Alverse Reactions

Psychiatric dynamics arranging from anxiety, paranoia, and depression to hallucinations and psychotic behavior can occur with metloquine use. Symptoms may occur early in the course of metloquine in some cases, these symptoms have been reported to continue for months or years after metloquine 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 caution in patients with a previous history of depression.

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.

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. Ketoconazole increases plasma concentrations and elimination half-life of mefloquine following coadministration (see CLINICAL PHARMACOLOGY, Pharmacokinetics, Elimination and PRECAUTIONS, Drug Interactions).

Mefloquine 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.

Chong-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 a prolonger defects 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).

lenticular opacity at 12.5 mg/kg/day and higher) (see AMIMAL TUXICULUGY).

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 silent ECG alterations have been reported during the use of mefloquine; alterations included sinus bradycardia, sinus arrhythmia, first degree AV-block, prolongation of the OTc 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.

Hypersensitivity Reactions
Hypersensitivity reactions have been reported with mefloquine use.

PRECAUTIONS

Should be weighed against the possibility of adverse enects in patients with cardiact iosiasese. 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
melfloquine has been reported, predominantly in areas of multi-drug resistance in South-East Asia.
Cross-resistance between mefloquine and halofantrine and cross-resistance between mefloquine and
quinine have been observed in some regions. 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 prophylaxi

possibility of adverse effects in patients with cardiac disease.
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).
Other Antimalarial Drugs Concomitant administration of mefloquine and other related antimalarial compounds (e.g., quinine, quinidine and chloroquine) may produce electrocardiographic abnormalities and increase the risk of convulsions (see WARNINGS). If these drugs are to be used in the initial treatment of severe malaria, mefloquine administration should be delayed at least 12 hours after the last dose. Clinically significant 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_{max} 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

Anticonvulsants

· that insomnia may occur

Carcinogenesis, Mutagenesis, Impairment of Fertility
Carcinogenesis: The carcinogenic potential of melloquine 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 female at doses of 20 and 50 mg/kg/day, Histopathiological lesions were noted in the epididymiderom male rats at doses of 20 and 50 mg/kg/day, Administration of 250 mg/week of mefloquies (base) in adult males for 22 weeks failed to reveal any deleterious effects on human spermatozoa.

(Dase) in auum imperior pregnancy Pregnancy 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 pregnancy. 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 if clearly needed.

both the possibility of traility, interloquine should be used untility prefacts of the 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 mataria 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 medull aoblogada 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

Melloquine 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 melloquine 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.

Administrated to a husing 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 trials 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.

Cardiac effects in electry patients.

ADVERSE REACTIONS

Clinical

At the doses used for treatment of acute malaria infections, the symptoms possibly attributable to drug administration cannot be distinguished from those symptoms usually attributable to the disease itself. Among subjects who received mefloquine for prophylaxis of malaria, the most frequently observed adverse experience was vomiting (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 single prophylactic dose of melloquine while concomitantly using propranolol (see PRECAUTIONS, Drug Interactions), and encephalopathy of unknown etiology during prophylactic melloquine administration. The relationship of encephalopathy to drug administration could not be clearly established.

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, purrutus, asthenia, transient emotional disturbances and telogen effluvium (loss of resting hair). Seizures have also been reported.

Laboratory
The most frequently observed laboratory alterations which could be possibly attributable to drug administration were decreased hematorit, 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.

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.

Other less frequently reported adverse reactions include: 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.

Blood and Lymphatic System Disorders: agranulocytosis, aplastic anemia.

Symptoms: visual disturbances, asthenia, malaise, fatigue, fever, hyperhidrosis, chills, isia and loss of appetite. Other S dyspeps OVERNUUSABLE
Symptoms and Signs
In cases of overdosage with mefloquine, the symptoms mentioned under ADVERS may be more pronounced.

DUSAGE AND ADMINISTRATION
Malaria Treatment in Adults
Treatment of mild to moderate malaria in adults caused by mefloquine-susceptible strains of
F falciparum or by P. vivax: Dossage: 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.

Treatment
Patients should be managed by symptomatic and supportive care following mefloquine overdose.
There are no specific antidotes. Monitor cardiac function (if possible by ECG) and neuropsychiatric status. Provide symptomatic and intensive supportive treatment as required.

If a full-treatment course with mefloquine does not lead to improvement within 48 to 72 hour mefloquine should not be used for retreatment. An alternative therapy should be used. Similarly, previous prophylaxis with mefloquine failed, mefloquine should not be used for curative treatme (see INDICATIONS AND USAGE).

DESCRIPTION

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 nam of (R*, S*)*(e.)*-ca*2-piperidinyl-2.8-bis (trifluoromethyl)-4-quinolinemethanol hydrochloride. is a 2-aryl substituted chemical structural analog of quinine. The drug is a white to almost whit crystalline compound, slightly soluble in water. The structural formula is as follows:

C₁₇H₁₆F₆N₂O.HCI M.W.: 414.78 The inactive ingredients are colloidal silicon dioxide, corn starch, crospovidone, lactose monohydrate magnesium stearate, microcrystalline cellulose, pregelatinized starch, poloxamer and talc.

Metabolism: Mefloquine is extensively metabolized in the liver by the cytochrome P450 system. In vitro and in vivo studies strongly suggested that CYP3A4 is the major isoform involved.

Mefloquine crosses the placenta. Excretion into breast milk appears to be minimal (see **PRECAUTIONS**, **Nursing Mothers**).

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. falciparum with decreased susceptibility to mefloquine can be selected in vitro or in vivo. Resistance of P. falciparum to mefloquine 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 mefloquine and halofantrine and cross-resistance between mefloquine and quinine have been observed in some regions.

QTc 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 QTc interval (see CLINICAL
PHARMACOLOGY, Pharmacokinetics, Elimination).

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 anternative 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 diving, while symptoms persist.

Information for Patients

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 dispensed. Patients should be instructed to read the Medication Guide when mefloquine is of superior 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 be advised: · that malaria can be a life-threatening infection that infloquine hydrochloride tablets are being prescribed to help prevent or treat this serious infection; 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;

 that when used as prophylaxis, the first dose of mefloquine hydrochloride tablets should be taken one week prior to arrival 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 (propranolo) (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.

interval (see WARNINGS).

Other Drugs that Prolong the OTc Interval
Coadministration of other drugs known to alter cardiac conduction (e.g., anti-arrhythmic or betaadrenergic blocking agents, calcium channel blockers, antihistamines or H₁-blocking agents, tricyclic
antidepressants and phenothiazines) might also contribute to a prolongation of the OTc 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.

Amuconvulsants
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 sking anti-seizure medication and mefloquine should have the blood level of their anti-seizure medication monitored and the dosage adjusted appropriately (see PRECAUTIONS).

should have the blood level of their anti-seizure medication monitored and the dubage adjusted appropriately (see PRECAUTIONS).

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 tablets.

Rifampin (Potent Inducer of CYP344)

Coadministration of a single 500 mg oral dose of mefloquine and 600 mg of rifampin once daily for 7 days in 7 healthy Thai volunteers resulted in a decrease in the mean C_{max} and AUC of mefloquine by 19% and 68%, respectively, and a decrease in the mean mean C_{max} and AUC of mefloquine by 19% and 68%, respectively, and a decrease in the mean mean C_{max} and AUC of mefloquine from 305 hours to 113 hours. Rifampin should be used cautiously in patients taking mefloquine from 305 hours to 113 hours. Rifampin should be used cautiously in patients taking mefloquine from 405 hours to 113 hours. Rifampin should be used cautiously in patients taking mefloquine from 405 hours to 113 hours. Rifampin should be used cautiously in patients taking mefloquine from 405 hours to 113 hours. Rifampin should be used cautiously in patients taking mefloquine in mefloquine playing the pharmacokinetics/metablosim of mefloquine, leading to an increase in mefloquine plasma concentrations and potential risk of adverse reactions. Therefore, mefloquine plasma concentrations and potential risk of adverse reactions. Therefore, mefloquine plasma concentrations and potential reduction in efficacy of mefloquine plasma concentrations and potential reduction in efficacy of mefloquine plasma concentrations and potential reduction in efficacy of mefloquine to a decrease in mefloquine plasma concentrations and potential reduction in efficacy of mefloquine in the proprietal plasma concentrations and potential reduction in efficacy of mefloquine in the proprietal plasma concentrations and potential reduction in eff

Useri established.

In several studies, the administration of mefloquine for the treatment of malaria was associated with early vomiting in pediatric patients. Early vomiting 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). Of time (see WARRINGS and BOOKET TO A CONTROLL TO A CONTRO

Because of the long half-life of mefloquine, adverse reactions to mefloquine may occur or per to several weeks after discontinuation of the drug. To several vectors and the control of the control o

The most frequently reported adverse reactions are nausea, vomiting, loose stools or diarrhea abdominal pain, dizziness or vertigo, loss of balance, and neuropsychiatric events such as headache somnolence, and sleep disorders (insomnia, abnormal dreams). These adverse reactions may occur arry in the course of mefloquine use. It has been reported that dizziness or vertigo, tinnitus and hearing impairment, and loss of balance may continue for months or years after discontinuation of 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.

Skin Disorders: rash, exanthema, erythema, urticaria, pruritus, edema, hair loss, erythema multiforme, and Stevens-Johnson syndrome. 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.

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).

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Malaria Prophylaxis in Adults Dosage: One 250 mg mefloqui uine hydrochloride tablet once weekly Prophylactic drug administration should begin 1 week before arrival in an endemic area. Subsequent weekly doses should be taken regularly, always on the same day of each week, preferably after the main meal. To reduce the risk of malaria after leaving an endemic area, prophylaxis must be continued for 4 additional weeks to ensure suppressive blood levels of the drug when merozoites emerge from the liver. Tablets should not be taken on an empty stomach and should be administered with at least 8 oz (240 mL) of water. In certain cases, e.g., when a traveler is taking other medication, it may be desirable to prophylaxis 2 to 3 weeks prior to departure, in order to ensure that the combination of drugs is tolerated (see **PRECAUTIONS**, **Drug Interactions**). When prophylaxis with mefloquine fails, physicians should carefully evaluate which antimalari use for therapy. Malaria Treatment in Pediatric Patients
Treatment of mild to moderate malaria in pediatric patients caused by mefloquine-susceptible strains
of P. falciparum: Dosage: 20 to 25 mg/kg body weight. Splitting the total therapeutic dose into 2 doses
taken 6 to 8 hours apart may reduce the occurrence or severity of adverse effects. The pediatric dose
should not exceed the adult dose. Experience with mefloquine in pediatric patients weighing less than 20 kg is limited. The drug should not be taken on an empty stomach and should be administered with ample water. The tablets may be crushed and suspended in a small amount of water, milk or other beverage for administration to small children and other persons unable to swallow them whole. 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, if previous prophylaxis with mefloquine has failed, mefloquine should not be used for curative treatment. In pediatric patients, the administration of mefloquine for the treatment of malaria has been associated with early vomiting. In some cases, early vomiting has been cited as a possible cause of treatment failure (see PRECAUTIONS). If a significant loss of drug product is observed or suspected because of vomiting, a second full dose of mefloquine should be administered to patients who vomities than 30 minutes after receiving the drug. If vomiting occurs 30 to 60 minutes after a dose, an additional half-dose should be given. If vomiting recurs, the patient should be monitored closely and alternative malaria treatment considered if improvement is not observed within a reasonable period of time. The safety and effectiveness of mef 6 months have not been established. of mefloquine to treat malaria in pediatric patients below the age of o motims have not been established.

Malaria Prophylaxis in Pediatric Patients
The recommended prophylactic dose of mefloquine is approximately 5 mg/kg body weight or weekly. One 250 mg mefloquine hydrochloride tablet should be taken once weekly in pediatric patien weighing over 45 kg. In pediatric patients weighing over 45 kg. In pediatric patients weighing over 45 kg. the weekly dose decreases proportion to body weight: 30 to 45 kg: 3/4 tablet 20 to 30 kg: 1/2 tablet Expe with mefloquine in pediatric patients weighing less than 20 kg is limited. HOW SUPPLIED
Melfloquine Hydrochloride Tablets USP, 250 mg are available as white, oval-shaped, flat-faced,
beveled-edge, scored tablets, debossed with b 171 on the scored side and plain on the other side,
packaged in unit-dose cartons of 25 tablets. Store at 20° to 25°C (68° to 77°F) [See USP Controlled Room Temperature]. KEEP THIS AND ALL MEDICATIONS OUT OF THE REACH OF CHILDREN. AMIMAL TOXICOLOGY

Ocular lesions were observed in rats fed mefloquine daily for 2 years. All surviving rats given 30 mg/kg/day had ocular lesions in both eyes characterized by retinal degeneration, opacity of the lens, and retinal edema. Similar but less severe lesions were observed in 80% of female and 22% of male rats fed 12.5 mg/kg/day for 2 years. At doses of 5 mg/kg/day, only corneal lesions were observed. They occurred in 9% of rats studied. Male Wistar rats orally administered-mefloquine daily for 22 days at the equivalent human therapeutic plasma concentration showed CNS penetration of mefloquine, with a 30-50 fold greater brain/plasma drug ratio up to 10 days after the final dose administered. 1 REFERENCES

1. Baudry S., Pham YT., Baune B., Vidrequin S., Crevoisier CH., Gimenez F., Fainotti R. (1997). Stereoselective passage of mefloquine through the blood brain barrier in the rat. *J. Pharm. Pharmacol.* 49: 1086-1090. TEVA PHARMACEUTICALS USA Sellersville, PA 18960 Medication Guide Mefloquine Hydrochloride Tablets USP Important:
Your doctor or pharmacist will give you an Information Wallet Card along with this Medication
Guide. It has important information about mefloquine and should be carried with you at all times
while you take mefloquine. Heart Problems
 Do not take halofa
 mefloquine or withi 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 OT prolongation) that can lead to death. Do not take quinine (Qualaquin) or quindine (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) depression 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. Problems with your body's nervous system. Symptoms of serious nervous system problems may include: dizzinece a feeling that you or things around you are 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 after you return from a malaria area. If you are told by a doctor to stop taking melloquine 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 leaving the malaria area may not protect you from getting malaria. Vou 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-tineatening 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 ha 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 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 melloquine? Before taking melloquine? Before taking melloquine, tell your doctor about all your medical conditions, including if you have: liver problems seizures or epilepsy diabetes 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 melloquine and for 3 months after you stop melloquine. If you have an unplanned pregnancy, talk to your doctor right away. are breastfeeding or plan to breastfeed. Melloquine can pass into your breast milk and may harm your baby. Ask your doctor if you will need to stop breastfeeding or use a different medicine. Contact your doctor right away if you have a fever after leaving a malaria area. Collect you declar that are in you take, including prescription and nonprescription medicines, vitamins, and herbal supplements. Mefloquine and other medicines may affect each other causing side effects. How should I take melloquine?

• Take melloquine exactly as your doctor tells you to take it. Your doctor will tell you how many melloquine tablets to take and when to take them. 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 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 take another dose.
 Continue taking mefloquine for 4 weeks after returning from a malaria area. Mefloquine tablets may be crushed and mixed with a small amount of water, milk or other beverage
for children or other people unable to swallow mefloquine whole. Your doctor will tell you the
correct dose for your child based on your child's weight. If you take mefloquine for a year or longer, your doctor should check your: · eyes (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 bitten mosquitoes. Medicine alone does not always stop you from catching malaria from mosquito bite wosquirioes, 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 heavy 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. See "What are the possible side effects of mefloquine?" What are the possible side effects of mefloquine?
See "What is the most important information I should know about mefloquine?" Mefloquine may cause serious side effects, including: • liver problems Call your healthcare provider right away if you have unexplained symptoms such as nausea or vomiting, stomach pain, fever, weakness, lichling, unusual tiredness, loss of appetile, 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 headache The most common side effects in people who take mefloquine for treatment include: muscle pain chills skin rash fatigue · loss of appetite irregular heart beat 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 doctor or pharmacist. Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088. How should I store mefloquine?
• Store mefloquine between 20°C to 25°C (68°F to 77°F) Safely throw away medicine that is out of date or no longer needed. Keep mefloquine and all medicines out of the reach of children. General information about the safe and effective use of mefloquine.

Medicines are sometimes prescribed for purposes other than those listed in a Medication Guide. It

ont use mefloquine for a condition for which it was not prescribed. Do not give mefloquine to oth

people, even if they have the same symptoms that you have. It may harm them. Do This Medication Guide summarizes the most important information about mefloquine. If you would like more information, talk with your doctor. You can ask your pharmacist or doctor for information about mefloquine that is written for health professionals. What are the ingredients in mefloquine hydrochloride tablets USP? Active ingredient: mefloquine hydrochloride Inactive ingredients: colloidal silicon dioxide, corn starch, crospovidone, lactose monohydrate, magnesium stearate, microcrystalline cellulose, pregelatinized starch, poloxamer and talc. This Medication Guide has been approved by the U.S. Food and Drug Administration TEVA PHARMACEUTICALS USA Sellersville, PA 18960 Rev. B 6/2013 Mefloquine Hydrochloride Tablets USP (mefloquine) Information Wallet Card 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 medicine before you travel to a malaria area, while you are in a malaria area, and after you return from a malaria area. These serious mental and nervous system side effects can go on for months or years after mefloquine is stopped or may become permanent in some people. Mefloquine can caus including: 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. 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 that can lead to death. Do not take quinine (Qualaquin) or quinidime (used to treat malaria or irregular heart beat) with mefloquine. You may get serious heart problems. Mefloquine may cause serious problems with the electrical system of your heart, called OT prolongation.

2. Mental problems. Symptoms of serious 1. Heart problems If you do not have access to a doctor or to a different medicine and have to stop taking mefloquine, leave the malaria area and contact a doctor as soon as possible because leaving the malaria area may not protect you from getting malaria. You will still need to take a malaria prevention medicine for another 4 weeks after you leave the malaria area. you leave the maaria area.

Mefloquine may cause serious liver problems
Symptoms of liver problems include nausea,
vomiting, loss of appetite, unusual tiredness,
stomach pain, fever, weakness, itching, lightcolored 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, dlarrhea, abdominal
pain and headache. heart, called QT prolongation.

2. Mental problems. Symptoms of serious mental problems may include severe anxiety, paranoia (feelings of mistrust towards others), hallucinations (seeling or hearing things that are not there), depression, feeling restless, unusual behavior or feeling confused. Some people who take mefloquine think about suicide (putting an end to their life). Some people who take mefloquine ommitted suicide. It is not known if mefloquine was responsible for those suicides. Pown and IndudCITE.

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 doctor or pharmacist. If you have any of these serious 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. Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088. 1-800-FDA-1088. What should lavoid while taking melloquine? Avoid activities such as driving a car or using heavy machinery or other activities needing alertness and careful movements (fine motor coordination) until you know how melloquine affects you. You may feel dizzy or lose your balance. This could happen for months or years after you stop taking melloquine and can be permanent in some cases. 3. Problems with your body's nervous system. Do not take quinine (Qualaquin) or chloroquine (Aralen) (used to treat malaria) with mefloquine. You may have a greater risk for convulsions (seizures). convuisions (selzures).

Symptoms of serious nervous system problems may include dizziness, a feeling that you or things around you are moving or spinning (vertigo), loss of balance, ringing in your ears (tinnitus), convulsions (seizures) in people who already have seizures, or you are unable to sleep (insomnia). TEVA PHARMACEUTICALS USA Sellersville, PA 18960 Rev. B 6/2013



Medication Guide Mefloquine Hydrochloride Tablets USP (mefloquine) to Prevent Malaria

MEDICATION GUIDE

Mefloquine Hydrochloride Tablets USP

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, including:

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 What is mefloquine? heart problems (problems with the electrical Mefloquine is a prescription medicine used (Qualaquin) or quinidine (used to treat malaria not work for all types of malaria. or irregular heart beat) with mefloquine. You may get serious heart problems.

- mental problems may include: severe anxiety
- paranoia (feelings of mistrust towards others) • hallucinations (seeing or hearing things

 Do not take mefloquine if you have:
- depression
- feeling restless unusual behavior
- feeling confused

Some people who take mefloquine think about suicide (putting an end to their life). Some
• an allergy to quinine, quinidine, mefloquine people who were taking mefloquine committed suicide. It is not known if mefloquine was responsible for those suicides.

problems, or you develop other serious mefloquine if you have any of the medical 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. system. Symptoms of serious nervous

- system problems may include: dizziness
- moving or spinning (vertigo) loss of balance
- ringing sound in your ears (tinnitus)
- convulsions (seizures) in people who mental problems 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)

Information Wallet Card

1. Heart problems.

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)

Carry this wallet card with you when you are taking mefloquine

r hearing things that are not there), depression, in some people.

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

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

or ketoconazole (used for fungal infections) with Do not take quinine (Qualaquin) or chloroqui

nefloquine. You may get serious heart problems that I may have a greater risk for convulsions (seizures).

nefloquine or within 15 weeks of your last dose of (Aralen) (used to treat malaria) with mefloquine. You

can 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

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

lems 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

or hearing things that are not unerely, depression, 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 under think about suicide (putting an end to their life). Some people who were under think about suicide (putting an end to their life). Some people who were under think about suicide (putting an end to their life). Some people who were under think about suicide (putting an end to their life). Some people who were under think about suicide (putting an end to their life). Some people who were under think about suicide (putting an end to their life). Some people who were under think about suicide (putting an end to their life). Some people who were under think about suicide (putting an end to their life). Some people who were under think about suicide (putting an end to their life).

to sleep (insomnia).

a malaria area.

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

Important:

You need to take malaria prevention | Mefloquine Hydrochloride Tablets USP 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 leaving 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.

system of your heart called QT prolongation) to prevent and treat malaria. Malaria can be that can lead to death. Do not take quinine a life-threatening infection. Mefloquine does It is not known if mefloquine is safe and

effective in children under 6 months old for the 2. Mental problems. Symptoms of serious treatment of malaria. It is not known how well mefloquine works to prevent malaria in children weighing less than 44 pounds (20 kilograms).

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
- or any ingredients in mefloquine. See the end of this Medication Guide for a complete list of ingredients in mefloquine.

If you have any of these serious mental Talk to your doctor before you take conditions listed above. What should I tell my doctor before taking

mefloquine? Before taking mefloquine, tell your 3. Problems with your body's nervous doctor about all your medical conditions, including if you have:

- heart disease liver problems
- a feeling that you or things around you are
 seizures or epilepsy
 - diabetes
 - blood clotting problems or take blood thinner medicines (anticoagulants)

different medicine to prevent malaria

- are pregnant or plan to become pregnant. I 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 mportant

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

Your doctor or pharmacist will give you an

should know about mefloquine? Mefloquine can cause serious side effects, 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 quinine (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)
- depression

dizziness

loss of balance

Information Wallet Card

Heart problems.

 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 mefloquine if you have any of the medical 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:

 - moving or spinning (vertigo) diabetes
- ringing sound in your ears (tinnitus) convulsions (seizures) in people who

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

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

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 chloroqui

efloquine. You may get serious heart problems that I may have a greater risk for convulsions (seizures).

can 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

problems. Mefloquine may cause serious problems

| Mefloquine may cause serious problems | problems

with the electrical system of your heart, called QT in people who already have seizures, or you are unable

Mental problems. Symptoms of serious mental These serious mental and nervous system side

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 will need to take a different malaria medicine.

olems may include severe anxiety, paranoia (feelings | effects can go on for months or years after

nistrust towards others), hallucinations (seeing mefloquine is stopped or may become permanent

to sleep (insomnia).

efloquine or within 15 weeks of your last dose of (Aralen) (used to treat malaria) with mefloquine. You

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.

Carry this wallet card with you when you are taking mefloquine

Mefloquine Hydrochloride Tablets USP (mefloquine)

Do not take halofantrine (used to treat malaria)

hearing things that are not there), depression, in some people.

You need to take malaria prevention | Mefloquine Hydrochloride Tablets USP medicine before you travel to a malaria area, while you are in a malaria area, and Information Wallet Card along with this after you return from a malaria area.

- 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
- What is the most important information I should know about mefloquine? another medicine and have to stop taking Mefloquine can cause serious side effects, mefloquine, leave the malaria area and contact a doctor as soon as possible because 1. Heart Problems. leaving the malaria area may not protect you Do not take halofantrine (used to treat malaria) from getting malaria. You will still need to

arphi medication guide

you at all times while you take mefloquine.

mental problems may include:

paranoia (feelings of mistrust towards others)

Some people who take mefloquine think about

people who were taking mefloquine committed

suicide. It is not known if mefloquine was

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.

system. Symptoms of serious nervous

severe anxiety

depression

feeling restless

unusual behavior

feeling confused

responsible for those suicides.

system problems may include:

(Aralen) with mefloquine

unable to sleep (insomnia)

permanent in some people.

Information Wallet Card

Heart problems.

Mefloquine Hydrochloride Tablets USP (mefloquine)

Do not take halofantrine (used to treat malaria)

moving or spinning (vertigo)

dizziness

loss of balance

or ketoconazole (used for fungal infections) take malaria prevention medicine for another

with mefloquine or within 15 weeks of your 4 weeks after you leave the malaria area. last dose of mefloquine. You may get serious What is mefloquine? What is mefloquine? Mefloquine is a prescription medicine used to prevent and treat malaria. Malaria can be that can lead to death. Do not take quinine a life-threatening infection. Mefloquine does (Qualaquin) or quinidine (used to treat malaria not work for all types of malaria. or irregular heart beat) with mefloquine. You It is not known if mefloquine is safe and may get serious heart problems. effective in children under 6 months old for the **2. Mental problems**. Symptoms of serious

weighing less than 44 pounds (20 kilograms). Who should not take mefloquine? Do not take mefloquine if you have:

 had recent mental problems, including anxiety disorder, schizophrenia, or psychosis (losing touch with reality) seizures or had seizures (epilepsy or

treatment of malaria. It is not known how well

mefloquine works to prevent malaria in children

depression or had depression recently

convulsions) an allergy to quinine, quinidine, mefloquine 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 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
- a feeling that you or things around you are seizures or epilepsy
 - blood clotting problems or take blood ringing sound in your ears (tinnitus) thinner medicines (anticoagulants) 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 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.

vou should contact your doctor right away as it may

different medicine to prevent malaria.

3. Problems with your body's nervous system

mportant:

You need to take malaria prevention medicine before you travel to a malaria Your doctor or pharmacist will give you an area, while you are in a malaria area, and 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 about mefloquine and should be carried with 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 leaving the malaria area may not protect you from getting malaria. You will still need to

4 weeks after you leave the malaria area.

heart problems (problems with the electrical Mefloquine is a prescription medicine used system of your heart called QT prolongation) to prevent and treat malaria. Malaria can be a life-threatening infection. Mefloquine does not work for all types of malaria.

> 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).

• hallucinations (seeing or hearing things Do not take mefloquine if you have:

• had recent mental problems, including anxiety disorder, schizophrenia, or psychosis (losing touch with reality) seizures or had seizures (epilepsy or

If you have any of these serious mental Talk to your doctor before you take problems, or you develop other serious mefloquine if you have any of the medical conditions listed above.

Before taking mefloquine, tell your 3. Problems with your body's nervous doctor about all your medical conditions,

- heart disease
- liver problems
- a feeling that you or things around you are seizures or epilepsy
 - thinner medicines (anticoagulants) mental problems
- are pregnant or plan to become pregnant. I is not known if mefloquine will harm your unborn baby. Talk to your doctor if you are treat malaria) with mefloquine. Do not pregnant or plan to become pregnant
- take quinine (Qualaquin) or chloroquine **stop mefloquine.** If you have an unplanned pregnancy, talk to your doctor right away.

Important:

Your doctor or pharmacist will give you an area, while you are in a malaria area, and 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 leaving the malaria area may not protect you take malaria prevention medicine for another 4 weeks after you leave the malaria area.

Mefloquine is a prescription medicine used

mefloquine works to prevent malaria in children weighing less than 44 pounds (20 kilograms).

- anxiety disorder, schizophrenia, or psychosis (losing touch with reality) feeling confused
- or any ingredients in mefloquine. See

problems, or you develop other serious mefloquine if you have any of the medical conditions listed above.

Before taking mefloquine, tell your including if you have:

- thinner medicines (anticoagulants)
- mental problems are pregnant or plan to become pregnant. It is not known if mefloquine will harm your
- 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.

You need to take malaria prevention | Mefloquine Hydrochloride Tablets USP medicine before you travel to a malaria

MEDICATION GUIDE

Your doctor or pharmacist will give you an Information Wallet Card along with this after you return from a malaria area.

should know about mefloquine?

Medication Guide. It has important information • If you are told by a doctor to stop taking mefloquine because of the side effects of about mefloquine and should be carried with for other reasons, you will need to take you at all times while you take mefloquine. different malaria medicine. What is the most important information I

You need to take malaria prevention

medicine before you travel to a malaria

area, while you are in a malaria area, and

mportant:

 If you do not have access to a doctor or to another medicine and have to stop taking Mefloquine can cause serious side effects, mefloquine. leave the malaria area and contact a doctor as soon as possible because leaving the malaria area may not protect yo from getting malaria. You will still need to

What is mefloquine?

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 quinine (Qualaguin) or quinidine (used to treat malaria or irregular heart beat) with mefloquine. You

2. Mental problems. Symptoms of serious mental problems may include: severe anxiety • paranoia (feelings of mistrust towards others)

- depression
- feeling restless unusual behavio

suicide (putting an end to their life). Some
• an allergy to quinine, quinidine, mefloquine 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 Talk to your doctor before you take

problems, or you develop other serious mefloquine if you have any of the medical 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.

- system. Symptoms of serious nervous including if you have: system problems may include:
- dizziness

already have seizures (epilepsy)

(Aralen) with mefloquine

unable to sleep (insomnia)

permanent in some people.

- moving or spinning (vertigo) loss of balance
- ringing sound in your ears (tinnitus) • convulsions (seizures) in people who • mental problems
- convulsions (seizures) in people who take quinine or chloroquine (used to
 - mefloquine and for 3 months after you stop mefloquine. If you have an unplanned

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

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

• hallucinations (seeing or hearing things

Do not take mefloquine if you have: Who should not take mefloquine? depression or had depression recently

psychosis (losing touch with reality) seizures or had seizures (epilepsy or Some people who take mefloquine think about convulsions)

conditions listed above.

mefloquine? Before taking mefloquine, tell your 3. Problems with your body's nervous doctor about all your medical conditions,

> heart disease liver problems

 diabetes • blood clotting problems or take blood

are pregnant or plan to become pregnant.

pregnant or plan to become pregnant. You should use birth control while you tak

Information Wallet Card It is important that you read the entire Medication Guide for additional information on mefloquing 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.

Mefloquine can cause serious side effects, including: be necessary to stop taking mefloquine and use 1. Heart problems.

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 (Qualaguin) or chlorogic efloquine or within 15 weeks of your last dose of (Aralen) (used to treat malaria) with mefloquine. You loquine. You may get serious heart problems that may have a greater risk for convulsions (seizures). can lead to death. **Do not** take quinine (Qualaquin) | Symptoms of serious nervous system problems may

beat) with mefloquine. You may get serious heart vou are moving or spinning (vertigo), loss of balance oblems. **Mefloquine may cause serious problems** ringing in your ears (tinnitus), convulsions (seizu to sleep (insomnia).

r hearing things that are not there), depression, in some people.

different medicine to prevent malaria.

ketoconazole (used for fungal infections) with **Do not** take quinine (Qualaquin) or chloroqu nefloquine or within 15 weeks of your last dose of (Aralen) (used to treat malaria) with mefloquine. You efloquine. You may get serious heart problems that may have a greater risk for convulsions (seizures).

or quinidine (used to treat malaria or irregular heart include dizziness, a feeling that you or things around leat) with mefloquine. You may get serious heart you are moving or spinning (vertigo), loss of balance, problems. **Mefloquine may cause serious problems** ringing in your ears (tinnitus), convulsions (seizures)

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

to sleep (insomnia).

oblems 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 r hearing things that are not there), depression, in some people.

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

with the electrical system of your heart, called QT in people who already have seizures, or you are unable

1. Heart Problems. Do not take halofantrine (used to treat malaria) from getting malaria. You will still need to or ketoconazole (used for fungal infections) with mefloquine or within 15 weeks of your

a life-threatening infection. Mefloquine does It is not known if mefloquine is safe and may get serious heart problems. effective in children under 6 months old for the

Who should not take mefloquine? Do not take mefloquine if you have: depression or had depression recently

had recent mental problems, including

seizures or had seizures (epilepsy or convulsions)

complete list of ingredients in mefloquine. If you have any of these serious mental Talk to your doctor before you take

What should I tell my doctor before taking mefloquine? 3. Problems with your body's nervous doctor about all your medical conditions, **system.** Symptoms of serious nervous

> heart disease liver problems

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

> unborn baby. Talk to your doctor if you are pregnant or plan to become pregnant

unable to sleep (insomnia)

take quinine (Qualaquin) or chloroquine (Aralen) with mefloquine

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) Information Wallet Card It is important that you read the entire Medication Guide for additional information on mefloquing

1. Heart problems.

Do not take halofantrine (used to treat malaria) can lead to death. **Do not** take quinine (Qualaquin) Symptoms of serious nervous system problems may

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

take malaria prevention medicine for another

It is not known if mefloquine is safe and

depression or had depression recently feeling restless

convulsions) suicide (putting an end to their life). Some
• an allergy to quinine, quinidine, mefloquine or any ingredients in mefloquine. See the end of this Medication Guide for a complete list of ingredients in mefloquine.

What should I tell my doctor before taking

including if you have:

 diabetes • blood clotting problems or take blood

You should use birth control while you take mefloquine and for 3 months after you

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

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 if

medicine before you travel to a malaria area, while | mefloquine was responsible for those suicides.

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

different medicine to prevent malaria. 3. Problems with your body's nervous system ketoconazole (used for fungal infections) with **Do not** take quinine (Qualaquin) or chloroqu efloquine or within 15 weeks of your last dose of (Aralen) (used to treat malaria) with mefloquine. You

rfloquine. You may get serious heart problems that I may have a greater risk for convulsions (seizures). can 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 you are moving or spinning (vertigo), loss of balance, 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 to sleep (insomnia).

you should contact your doctor right away as it may

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 permanent hearing things that are not there), depression, in some people.

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

about mefloquine and should be carried with you at all times while you take mefloquine. What is the most important information I

Important:

MEDICATION GUIDE

Mefloquine Hydrochloride Tablets USP

should know about mefloquine? Mefloquine can cause serious side effects,

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 What is mefloquine? heart problems (problems with the electrical system of your heart called QT prolongation) to prevent and treat malaria. Malaria can be that can lead to death. Do not take quinine (Qualaquin) or quinidine (used to treat malaria not work for all types of malaria. or irregular heart beat) with mefloquine. You

may get serious heart problems. 2. Mental problems. Symptoms of serious treatment of malaria. It is not known how well mental problems may include: severe anxiety

unusual behavio

responsible for those suicides.

 paranoia (feelings of mistrust towards others) hallucinations (seeing or hearing things that are not there) depression

 feeling confused Some people who take mefloquine think about suicide (putting an end to their life). Some
• an allergy to quinine, quinidine, mefloquine people who were taking mefloquine committed suicide. It is not known if mefloquine was the end of this Medication Guide for a

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.

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

system problems may include:

 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

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. you are in a malaria area, and after you return from I If you have any of these serious mental proble you should contact your doctor right away as it may

3. Problems with your body's nervous system

4 weeks after you leave the malaria area. Mefloquine is a prescription medicine used to prevent and treat malaria. Malaria can be a life-threatening infection. Mefloquine does

take malaria prevention medicine for another

mefloquine works to prevent malaria in children weighing less than 44 pounds (20 kilograms). had recent mental problems, including

anxiety disorder, schizophrenia, o

or any ingredients in mefloquine. See the end of this Medication Guide for a complete list of ingredients in mefloquine.

What should I tell my doctor before taking

thinner medicines (anticoagulants)

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

different medicine to prevent malaria.

with the electrical system of your heart, called QT in people who already have seizures, or you are unable . Mental problems. Symptoms of serious mental | These serious mental and nervous system side oblems 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

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 will need to take a different malaria medicine.

• a feeling that you or things around you are
• seizures or epilepsy

pregnancy, talk to your doctor right away.

Mefloquine Hydrochloride Tablets USP (mefloquine

you are in a malaria area, and after you return from If you have any of these serious mental proble you should contact your doctor right away as it may

or quinidine (used to treat malaria or irregular heart include dizziness, a feeling that you or things arou

are breastfeeding or plan to breastfeed. Call your healthcare provider right away if you 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

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?

use a different medicine

- 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 when to take them.
- 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 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 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 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. your 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 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 **hvdrochloride tablets USP?** vears 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, See "What is the most important information This Medication Guide has been approved

loss of annetite unusual tiredness, stomach pain, fever

weakness, itching, light-colored bowel movements,

yellowing of your skin or the

I should know about mefloquine?' Mefloquine may cause serious side effects, including:

liver problems

vou leave the malaria area.

abdominal pain and headache.

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

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

a condition for which it was not prescribed.

This Medication Guide summarizes the most

important information about mefloquine. If

pregelatinized starch, poloxamer and talc.

What should I avoid while taking mefloquine?

know how mefloquine affects you. You may feel dizzy

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 bothers you or that does not go away. These are not

malaria area and contact a doctor as soon as possible all the possible side effects of mefloquine. For more

you from getting malaria. You will still need to take a Call your doctor for medical advice about side effects

Mefloquine may cause serious liver problems. Avoid activities such as driving a car or using heat

malaria prevention medicine for another 4 weeks after You may report side effects to FDA at 1-800-FDA-1088.

symptoms of liver problems include nausea, vomiting, machinery or other activities needing alertness and machinery or other activities needing alertness and

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.

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Sellersville, PA 18960

because leaving the malaria area may not protect information, ask your doctor or pharmacist.

Do not give mefloguine to other people.

abdominal pain

headache

fever

skin rash

fatique

loss of appetite

irregular heart beat

doctor or pharmacist.

FDA at 1-800-FDA-1088.

(68°F to 77°F)

the reach of children.

effective use of mefloquine.

you have. It may harm them.

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.

Mefloquine and other medicines may affect • diarrhea

each other causing side effects.

use a different medicine.

- muscle pain how many mefloquine tablets to take and when to take them
 - malaria between 1 to 3 weeks before you skin rash travel to a malaria area.
 - 1 cup (8 ounces) of water. Do not take mefloquine on an
 - If you vomit after taking mefloquine. contact your doctor to see if you should doctor or pharmacist.
 - Continue taking mefloquine for 4 weeks side effects. You may report side effects to

- - If you take mefloquine for a year or longer, the reach of children. your doctor should check your:
 - liver function (to see if there has been
 - malaria from mosquito bites.

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

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

I should know about mefloquine?' by the U.S. Food and Drug Administration. Mefloquine may cause serious side TEVA PHARMACEUTICALS USA effects, including: Sellersville, PA 18960 liver problems Rev. B 6/2013

Tell your doctor about all the medicines you include

take, including prescription and nonprescription • nausea medicines, vitamins, and herbal supplements. • vomiting

• are breastfeeding or plan to breastfeed. Call your healthcare provider right away if you

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

irregular heart beat

FDA at 1-800-FDA-1088.

effective use of mefloquine.

you have. It may harm them.

(68°F to 77°F)

headache

fever

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

a condition for which it was not prescribed.

even if they have the same symptoms that

This Medication Guide summarizes the most

important information about mefloquine. If

pregelatinized starch, poloxamer and talc.

by the U.S. Food and Drug Administration.

TEVA PHARMACEUTICALS USA

Do not give mefloguine to other people.

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: muscle pain

- You will start taking mefloquine to prevent chills fatigue
- Take mefloquine just after eating your loss of appetite largest meal of the day and with at least
- stomach
- take another dose.
- 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 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.
- eyes (especially if you have trouble
- seeing while you take mefloquine) 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

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 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,

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

ou leave the malaria area.

reakness, itching, light-colored bowel movements,

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Rev. B 6/2013

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

mefloquine?

effects, including:

liver problems

dicine and have to stop taking mefloquine, leave the bothers you or that does not go away. These are not laria 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. you from getting malaria. You will still need to take a Call your doctor for medical advice about side effects. ialaria prevention medicine for another 4 weeks after You may report side effects to FDA at 1-800-FDA-1088. vou leave the malaria area. What should I avoid while taking mefloquine?

Mefloquine may cause serious **liver problems**. Avoid activities such as driving a car or using heavy machinery or other activities needing alertness and ss of appetite, unusual tiredness, stomach pain, fever. careful movements (fine motor coordination) until you veakness, itching, light-colored bowel movements, weakness, itching, light-colored bower 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, permanent in some cases. dark colored urine, yellowing of your skin or the bdominal pain and headache.

you do not have access to a doctor or to a different Tell your doctor if you have any side effect that licine and have to stop taking mefloquine, leave the I 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 mor cause 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

nalaria 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? Mefloquine may cause serious liver problems. Avoid activities such as driving a car or using hear

pregelatinized starch, poloxamer and talc.

by the U.S. Food and Drug Administration.

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nptoms of liver problems include nausea, vomiting, machinery or other activities needing alertness and machinery or other activities needing alertness and 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, and headache.

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.

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: when to take them You will start taking mefloquine to prevent

travel to a malaria area.

largest meal of the day and with at least 1 cup (8 ounces) of water. Do not take mefloquine on an

• If you vomit after taking mefloquine. doctor or pharmacist. contact your doctor to see if you should take another dose.

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 unable to swallow mefloquine whole. Your • Safely throw away medicine that is out of doctor will tell you the correct dose for your 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: eves (especially if you have trouble

effective use of mefloquine.

What should I avoid while taking mefloquine?

mefloquine? I should know about mefloquine?"

effects, including: liver problems

ou leave the malaria area.

• are breastfeeding or plan to breastfeed. Call your healthcare provider right away if you 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

muscle pain

loss of appetite

irregular heart beat

FDA at 1-800-FDA-1088.

date or no longer needed.

you have. It may harm them.

(68°F to 77°F)

fever

skin rash

fatigue

a fever after leaving a malaria area.

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

malaria between 1 to 3 weeks before you Take mefloquine just after eating your

stomach.

Continue taking mefloquine for 4 weeks

seeing while you take mefloquine) Medicines are sometimes prescribed • liver function (to see if there has been for purposes other than those listed in a damage to your liver) Medication Guide. Do not use mefloquine for

 Use protective clothing, insect repellents, a condition for which it was not prescribed. and bed nets to protect you from being Do not give mefloquine to other people. bitten by mosquitoes. Medicine alone even if they have the same symptoms that does not always stop you from catching malaria from mosquito bites.

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,

See "What is the most important information Mefloquine may cause serious side

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

This Medication Guide summarizes the most

important information about mefloquine. If

pregelatinized starch, poloxamer and talc.

What should I avoid while taking mefloquine?

careful movements (fine motor coordination) until vo

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

alaria prevention medicine for another 4 weeks after You may report side effects to FDA at 1-800-FDA-1088.

loquine may cause serious liver problems. Avoid activities such as driving a car or using hear

weakness, itcning, light-colored bower movements the dark colored urine, yellowing of your skin or the white of your eyes. The most **common side effects** or lose your balance. This could happen for months or years after you stop taking mefloquine and can be permanent in some cases.

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ptoms of liver problems include nausea, vomiting, machinery or other activities needing alertness and

ause leaving the malaria area may not protect information, ask your doctor or pharmacist.

licine and have to stop taking mefloquine, leave the | bothers you or that does not go away. These are not laria area and contact a doctor as soon as possible all the possible side effects of mefloquine. For mo

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by the U.S. Food and Drug Administration.

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?

use a different medicine.

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

 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 1 cup (8 ounces) of water. Do not take mefloquine on an

stomach. • If you vomit after taking mefloquine. contact your doctor to see if you should doctor or pharmacist.

take another dose. side effects. You may report side effects to | • 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. your 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 bitten by mosquitoes. Medicine alone malaria from mosquito bites. What should I avoid while taking

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 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 Rev. B 6/2013

• are breastfeeding or plan to breastfeed. Call your healthcare provider right away if you 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

skin rash fatigue

 loss of appetite irregular heart beat 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 FDA at 1-800-FDA-1088

Keep mefloquine and all medicines out of

General information about the safe and effective use of mefloquine.

Medicines are sometimes prescribed for purposes other than those listed in a Medication Guide. Do not use mefloquine for a condition for which it was not prescribed. Do not give mefloquine to other people. 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

pregelatinized starch, poloxamer and talc.

by the U.S. Food and Drug Administration. TEVA PHARMACEUTICALS USA

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dedicine and have to stop taking mefloquine, leave the lalaria area and contact a doctor as soon as possible all the possible side effects of mefloquine. For more ou leave the malaria area. Mefloquine may cause serious liver problems. Avoid activities such as driving a car or using heavy

ss of appetite, unusual tiredness, stomach pain, fever, weakness, itching, light-colored bowel movements, ark colored urine, yellowing of your skin or the odominal pain and headache.

cause 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 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?

mptoms of liver problems include nausea, vomiting, machinery or other activities needing alertness and careful movements (fine motor coordination) until voi 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, and headache.

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

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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

• 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

does not always stop you from catching even if they have the same symptoms that

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

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,

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

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

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

coordination) until you know how mefloquine that is written for health professionals.

balance. This could happen for months or hydrochloride tablets USP?

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.

abdominal pain

headache

muscle pain

fever

skin rash

fatique

loss of appetite

irregular heart beat

FDA at 1-800-FDA-1088.

effective use of mefloquine.

you have. It may harm them.

use a different medicine.

each other causing side effects.

when to take them

take another dose.

stomach.

travel to a malaria area.

1 cup (8 ounces) of water.

Do not take mefloquine on an

How should I take mefloquine?

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

how many mefloquine tablets to take and

You will start taking mefloquine to prevent

Take mefloquine just after eating your

• If you vomit after taking mefloquine.

after returning from a malaria area.

child based on your child's weight.

eves (especially if you have trouble

liver function (to see if there has been

Use protective clothing, insect repellents,

and bed nets to protect you from being

bitten by mosquitoes. Medicine alone

What should I avoid while taking

seeing while you take mefloquine)

your doctor should check your:

damage to your liver)

malaria from mosquito bites.

I should know about mefloquine?"

Mefloquine may cause serious side

mefloquine?

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

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

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

largest meal of the day and with at least

malaria between 1 to 3 weeks before you

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s of appetite, unusual tiredness, stomach pain, fever,

eakness, itching, light-colored bowel movements,

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