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MEDICATION GUIDE
Mefloquine Hydrochloride Tablets

Read this entire Medication Guide before you start taking mefloquine and each time you get a refill. There may be new information. This information does not take the place of talking to your doctor about your medical condition or your treatment.

What is the most important information I should know about mefloquine?

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.

Mefloquine can cause serious mental problems.

- Some people who take mefloquine have sudden serious mental problems, including:
  - severe anxiety
  - paranoia (feelings of mistrust towards others)
  - hallucinations (seeing or hearing things that are not there)
  - depression
  - feeling restless
  - unusual behavior
  - feeling confused

In some patients these serious side effects can go on after Mefloquine is stopped.

- 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 whether 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 call your doctor right away as it may be necessary to stop taking mefloquine and use another medicine to prevent malaria.

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 mefloquine because of the side effects or for other reasons, you will need to take another 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 a malaria prevention medicine for another 4 weeks.

- 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 have serious heart problems that can lead to death. Do not take quinine (Qualaquin) or quinidine (used to treat malaria or irregular heart beat) with mefloquine. You may have serious heart problems.
- Do not take quinine (Qualaquin) or chloroquine (Aralen) (used to treat malaria) with mefloquine. You may have a greater risk for convulsions (seizures).

What is Mefloquine?

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

It is not known if mefloquine is safe and effective in children under 6 months old for the treatment of malaria.

It is not known how well mefloquine works to prevent malaria in infants weighing less than 44 lbs (20 kg).

Who should not take Mefloquine?

Do not take Mefloquine if you have:

- depression or had depression recently
- had recent mental problems, including anxiety disorder, schizophrenia, or psychosis (losing touch with reality)
- seizures or had seizures (epilepsy or convulsions)
- an allergy to quinine, quinidine, mefloquine 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 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
- 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 you doctor if you are pregnant or plan to become pregnant.
- 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.
- are breast-feeding or plan to breast-feed. Mefloquine can pass through your milk and may harm your baby. Ask your doctor whether you will need to stop breast-feeding or use another medicine.

After leaving a malaria area, if you have a fever contact your doctor right away.

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

Know the medicines you take. Keep a list of them and show it to your doctor and pharmacist when you get a new medicine.

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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.

Mefloquine can cause serious mental problems in some people. If you take Mefloquine and you have sudden signs of serious mental problems (such as: severe anxiety, feelings of mistrust towards others, seeing or hearing things that are not there, depression, feeling restless, unusual behavior or feeling confused), you should contact a doctor right away as it may be necessary to stop taking mefloquine and take different medicine to prevent malaria.

Other side effects from Mefloquine may include: convulsions, liver problems, and heart problems. The most common side effects of mefloquine include nausea, vomiting, diarrhea, abdominal pain, dizziness or loss of balance (vertigo) which may continue for months after mefloquine is stopped, headache, and sleeping problems (sleepiness, unable to sleep, bad dreams).

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- 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 conditions listed above.

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- heart disease
- 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 you doctor if you are pregnant or plan to become pregnant.
- 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.
- are breast-feeding or plan to breast-feed. Mefloquine can pass through your milk and may harm your baby. Ask your doctor whether you will need to stop breast-feeding or use another medicine.

After leaving a malaria area, if you have a fever contact your doctor right away.

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

Know the medicines you take. Keep a list of them and show it to your doctor and pharmacist when you get a new medicine.

(See Reverse)

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Other side effects from Mefloquine may include: convulsions, liver problems, and heart problems. The most common side effects of mefloquine include nausea, vomiting, diarrhea, abdominal pain, dizziness or loss of balance (vertigo) which may continue for months after mefloquine is stopped, headache, and sleeping problems (sleepiness, unable to sleep, bad dreams).

(See Reverse)

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Especially tell your doctor if you take:

- ketoconazole used to treat fungal infections
- halofantrine, quinine (Qualaquin), quinidine, chloroquine (Aralen) or other medicines used to treat malaria
- anti-arrhythmic medicines, beta-adrenergic blocking medicines and calcium channel blockers used to treat heart problems or high blood pressure
- antihistamines or H_1-blocking agents used to treat allergies
- tricyclic antidepressants used to treat depression
- phenothiazines used to treat mental problems
- anticonvulsants used to treat seizures
- vaccines containing live bacteria. Your doctor may want you to finish receiving your vaccines at least 3 days before you start mefloquine.
- rifampin and rifampin-containing products (Rifadin, Rifamate, Rifater, Rimactane) used to treat infections

Ask your doctor or pharmacist for a list of these medicines if you are not sure.

How should I take Mefloquine?

- Take mefloquine exactly as your doctor tells you to take it. Your doctor will tell you how many mefloquine hydrochloride 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 main meal and with at least one cup (8 ounces) of water.
- Do not take mefloquine on an empty stomach.
- If you vomit after taking mefloquine, call your healthcare provider 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 bednets to protect you from being bitten by mosquitoes. Medicine alone does not always stop you from catching malaria from mosquito bites.

What should I avoid while taking mefloquine?

Avoid activities such as driving a car or using 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 after you stop taking mefloquine. See "What are the possible side effects of mefloquine?"

What are the possible side effects of mefloquine?

Also see "What is the most important information I should know about mefloquine?"

Mefloquine may cause serious side effects, including:

- convulsions (seizures)
- liver problems
- heart problems

The most common side effects of mefloquine include:

- nausea
- vomiting
- diarrhea
- abdominal pain
- dizziness or loss of balance (vertigo), which may continue for months after mefloquine is stopped
- headache
- sleeping problems (sleepiness, unable to sleep, bad dreams)

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

- muscle pain
- fever
- chills
- skin rash
- fatigue
- loss of appetite
- ringing in the ears
- 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 59°F to 86°F (15°C to 30°C)
- 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. Do not use mefloquine for a condition for which it was not prescribed. Do not give mefloquine to other people, even if they have the same symptoms that you have. It may harm them.

This Medication Guide summarizes the most important information about mefloquine. If 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?

Active ingredients: mefloquine hydrochloride

Inactive ingredients: crospovidone, lactose monohydrate, low-substituted hydroxypropyl cellulose, magnesium stearate, microcrystalline cellulose, pregelatinized starch and talc.

This Medication Guide has been approved by the U.S. Food and Drug Administration.

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While you take Mefloquine, do not take:

- **Halofantrine (used to treat malaria)**
- **Ketoconazole (used for fungal infections)**
- **Quinine (Qualaquin) or quinidine (used to treat malaria or irregular heart beat)**
- **Chloroquine (Aralen) (used to treat malaria)**

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.

Other medicines are approved in the United States for malaria prevention. However, not all malaria medicines work equally well in different malaria areas. Before you travel, talk to your doctor about your travel plans.

If you have any serious side effects, and cannot get another medicine, 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.

Call your doctor for medical advice about side effects.

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Especially tell your doctor if you take:

- ketoconazole used to treat fungal infections
- halofantrine, quinine (Qualaquin), quinidine, chloroquine (Aralen) or other medicines used to treat malaria
- anti-arrhythmic medicines, beta-adrenergic blocking medicines and calcium channel blockers used to treat heart problems or high blood pressure
- antihistamines or H_1-blocking agents used to treat allergies
- tricyclic antidepressants used to treat depression
- phenothiazines used to treat mental problems
- anticonvulsants used to treat seizures
- vaccines containing live bacteria. Your doctor may want you to finish receiving your vaccines at least 3 days before you start mefloquine.
- rifampin and rifampin-containing products (Rifadin, Rifamate, Rifater, Rimactane) used to treat infections

Ask your doctor or pharmacist for a list of these medicines if you are not sure.

How should I take Mefloquine?

- Take mefloquine exactly as your doctor tells you to take it. Your doctor will tell you how many mefloquine hydrochloride 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 main meal and with at least one cup (8 ounces) of water.
- Do not take mefloquine on an empty stomach.
- If you vomit after taking mefloquine, call your healthcare provider 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 bednets to protect you from being bitten by mosquitoes. Medicine alone does not always stop you from catching malaria from mosquito bites.

What should I avoid while taking mefloquine?

Avoid activities such as driving a car or using 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 after you stop taking mefloquine. See "What are the possible side effects of mefloquine?"

What are the possible side effects of mefloquine?

Also see "What is the most important information I should know about mefloquine?"

Mefloquine may cause serious side effects, including:

- convulsions (seizures)
- liver problems
- heart problems

The most common side effects of mefloquine include:

- nausea
- vomiting
- diarrhea
- abdominal pain
- dizziness or loss of balance (vertigo), which may continue for months after mefloquine is stopped
- headache
- sleeping problems (sleepiness, unable to sleep, bad dreams)

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

- muscle pain
- fever
- chills
- skin rash
- fatigue
- loss of appetite
- ringing in the ears
- 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 59°F to 86°F (15°C to 30°C)
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Keep mefloquine and all medicines out of the reach of children.

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Other medicines are approved in the United States for malaria prevention. However, not all malaria medicines work equally well in different malaria areas. Before you travel, talk to your doctor about your travel plans.

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