



(Continued)

quine should not be used for curative treatment (see **INDICATIONS AND USAGE**).

*Note:* Patients with acute *P. vivax* malaria, treated with mefloquine, are at high risk of relapse because mefloquine does not eliminate exoerythrocytic (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 (eg, primaquine).

#### Malaria Prophylaxis in Adults

Dosage: One 250 mg mefloquine 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, eg, when a traveler is taking other medication, it may be desirable to start prophylaxis 2 to 3 weeks prior to departure, in order to ensure that the combination of drugs is well tolerated (see **PRECAUTIONS: Drug Interactions**).

When prophylaxis with mefloquine fails, physicians should carefully evaluate which antimalarial to 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 vomit less 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 mefloquine to treat malaria in pediatric patients below the age of 6 months have not been established.

#### Malaria Prophylaxis in Pediatric Patients

The recommended prophylactic dose of mefloquine is approximately 5 mg/kg body weight once weekly. One 250 mg mefloquine hydrochloride tablet should be taken once weekly in pediatric patients weighing over 45 kg. In pediatric patients weighing less than 45 kg, the weekly dose decreases in proportion to body weight:

30 to 45 kg: 3/4 tablet  
20 to 30 kg: 1/2 tablet

Experience with mefloquine in pediatric patients weighing less than 20 kg is limited.

#### HOW SUPPLIED

Mefloquine hydrochloride tablets USP, 250 mg are round, white to off white tablets, scored, debossed GP 118 on one side and plain on the reverse side, and are supplied as follows:

NDC 0781-5076-86 in Unit of Use pack of 25 tablets  
Store at 20°-25°C (68°-77°F) (see USP Controlled Room Temperature).

#### ANIMAL 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.

#### 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.

## 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.

**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 heart problems (problems with the electrical system of your heart called QT prolongation) that can lead to death. Do not take quinine (Qualaquin) or quinine (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.

3. **Problems with your body's nervous system.** 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 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 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 a malaria prevention medicine for another 4 weeks after you leave the malaria area.

#### What is Mefloquine?

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

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

#### Who should not take Mefloquine?

**Do not take Mefloquine if you have:**

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

- are breast-feeding or plan to breast-feed. Mefloquine can pass into your milk and may harm your baby. Ask your doctor if you will need to stop breast-feeding or use a different medicine.

**Contact your doctor right away if you have a fever after leaving a malaria area.**

**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.

#### How should I take Mefloquine?

- Take mefloquine exactly as your doctor tells you to take it. Your doctor will tell you 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 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 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, itching, unusual tiredness, loss of appetite, 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
- fever
- 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 at room temperature between 68°F to 77°F (20°C to 25°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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### Information Wallet Card: Mefloquine Hydrochloride Tablets, USP

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.**

**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 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 get serious heart problems.

**Mefloquine may cause serious problems with the electrical system of your heart, called QT prolongation.**

**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 or 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 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.

**Do not take** quinine (Qualaquin) or chloroquine (Aralen) (used to treat malaria) with mefloquine. You may have a greater risk for convulsions (seizures).

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).

**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.**

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.

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.

Mefloquine may cause serious **liver problems**. Symptoms of liver problems include nausea, vomiting, loss of appetite, unusual tiredness, stomach pain, fever, weakness, itching, light-colored bowel movements, dark colored urine, yellowing of your skin or the white of your eyes. The most **common side effects** of mefloquine include nausea, vomiting, diarrhea, abdominal pain and headache.

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.

#### 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.

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

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

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

**3. Problems with your body's nervous system.**

Symptoms of serious nervous system problems may include:

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- a feeling that you or things around you are moving or spinning (vertigo)

- loss of balance
- ringing sound in your ears (tinnitus)
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- 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 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 a malaria prevention medicine for another 4 weeks after you leave the malaria area.

**What is Mefloquine?**

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

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

**Who should not take Mefloquine?**

- Do not take Mefloquine if you have:**
- depression or had depression recently

(Continued)

of balance, ringing in your ears (tinnitus), convulsions (seizures) in people who already have seizures, or you are unable to sleep (insomnia).

**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.**

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.

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.

Mefloquine may cause serious **liver problems**. Symptoms of liver problems include nausea, vomiting, loss of appetite, unusual tiredness, stomach pain, fever, weakness, itching, light-colored bowel movements, dark colored urine, yellowing of your

skin or the white of your eyes. The most **common side effects** of mefloquine include nausea, vomiting, diarrhea, abdominal pain and headache.

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.

**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.

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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 medical conditions listed above.

**What should I tell my doctor before taking mefloquine?**

**Before taking mefloquine, tell your doctor about all your medical conditions, including if you have:**

- heart disease
  - liver problems
  - 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 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 into your milk and may harm your baby. Ask your doctor if you will need to stop breast-feeding or use a different medicine.
- Contact your doctor right away if you have a fever after leaving a malaria area.**

**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.

**How should I take Mefloquine?**

- Take mefloquine exactly as your doctor tells you to take it. Your doctor will tell you 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 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)
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**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:**

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- vomiting
- diarrhea
- abdominal pain
- headache

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

- muscle pain
- fever
- 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.

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**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.

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**2. Mental problems.** Symptoms of serious mental problems may include severe anxiety, paranoia (feel-

ings of mistrust towards others), hallucinations (seeing 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 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 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.**

**Do not** take quinine (Qualaquin) or chloroquine (Aralen) (used to treat malaria) with mefloquine. You may have a greater risk for convulsions (seizures).

Symptoms of serious nervous system problems may include dizziness, a feeling that you or things around you are moving or spinning (vertigo), loss

1.

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(See Reverse)

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