## PRODUCT MONOGRAPH

MEFLOQUINE

Mefloquine Hydrochloride Tablets

250 mg (as base)

## THERAPEUTIC CLASSIFICATION

Antimalarial Agent

## INFORMATION FOR THE PATIENT

**MEFLOQUINE Tablets to Prevent Malaria**

**This information for the Patient guide is intended only for travellers who are taking MEFLOQUINE to prevent malaria**. The information may not apply to patients who are sick with malaria and who are taking MEFLOQUINE to treat malaria.

An information wallet card is provided at the end of this document. Cut it out and carry it with you when you are taking MEFLOQUINE.

This document was revised in February 2009. Please read it before you start taking MEFLOQUINE and each time you get a refill. There may be new information. This document does not take the place of talking with your prescriber (doctor or other health care provider) about MEFLOQUINE and malaria prevention. Only you and your prescriber can decide if

MEFLOQUINE is right for you. If you cannot take MEFLOQUINE you may be able to take a different medicine to prevent malaria.

**What is MEFLOQUINE?**

MEFLOQUINE is the trade name for an antimalarial product containing the drug mefloquine.

Each MEFLOQUINE 250 mg tablet contains 250 mg of mefloquine (base) present as mefloquine hydrochloride. The non-medicinal ingredients are microcrystalline cellulose, magnesium stearate, croscarmellose sodium and colloidal silicon dioxide.

The tablets should be stored at 15-30 °C. The tablets are sensitive to moisture and should remain in their blister until consumed.

**What is the most important information I should know about MEFLOQUINE?**

**1. Take MEFLOQUINE exactly as prescribed to prevent malaria.**

Malaria is an infection that can cause death and is spread to humans through mosquito bites. If you travel to parts of the world where the mosquitoes carry the malaria parasite, you must take a malaria prevention medicine. MEFLOQUINE is one of a small number of medications approved to prevent and to treat malaria. If taken correctly, MEFLOQUINE is effective at preventing malaria but, like all medications, it may produce side effects in some patients.

**2. MEFLOQUINE can rarely cause serious mental problems in some patients.**

The most frequently reported side effects with MEFLOQUINE, such as nausea, difficulty sleeping, and bad dreams are usually mild and do not cause people to stop taking the medicine. However, people taking MEFLOQUINE occasionally experience severe anxiety, feelings that people are against them, hallucinations (seeing or hearing things that are not there for example), depression,

unusual behavior, or feeling disoriented. There have been reports that in some patients these side effects continue after MEFLOQUINE is stopped. Some patients taking MEFLOQUINE think about killing themselves, and there have been rare reports of suicides. It is not known whether MEFLOQUINE was responsible for these suicides.

**If you use MEFLOQUINE to prevent malaria and you develop a sudden onset of unexplained anxiety, depression, restlessness or irritability, or confusion (possible signs of more serious mental problems), or you develop other serious side effects, including a persistently abnormal heart beat or palpitations, contact a doctor or health care provider. It may be necessary to stop taking MEFLOQUINE and use another malaria prevention medicine instead. If you can't get another medicine, leave the malaria area. However, be aware that leaving the malaria area may not protect you from getting malaria. You still need to take a malaria prevention medicine.**

**3. 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.**

Medicines approved in Canada for malaria prevention include 'MEFLOQUINE', doxycycline, atovaquone/proguanil, hydroxychloroquine, and chloroquine. Not all of these drugs work equally as well in all areas of the world where there is malaria. The chloroquines, for example, do not work in areas where the malaria parasite has developed resistance to chloroquine. MEFLOQUINE may be effective against malaria that is resistant to chloroquine or other drugs. All drugs used to prevent malaria have side effects that are different for each one. For example, some may make your skin more sensitive to sunlight (MEFLOQUINE does not do this).

**General Precautions with MEFLOQUINE:**

Do not take MEFLOQUINE to **prevent** malaria if you

**- have or had depression**

- **have had recent mental illness or problems**, including anxiety disorder, schizophrenia (a severe type of mental illness), or psychosis (losing touch with reality)

**- have or had seizures (epilepsy or convulsions)**

**- are allergic to quinine or quinidine (medicines related to MEFLOQUINE)**

**Tell your prescriber about all your medical conditions.** MEFLOQUINE may not be right for you if you have certain conditions, especially the ones listed below:

- **Heart Disease.** MEFLOQUINE may not be right for you.

- **Pregnancy.** Tell your prescriber if you are pregnant or plan to become pregnant. It is dangerous for the mother and for the unborn baby (fetus) to get malaria during pregnancy. Therefore, ask your prescriber if you should take MEFLOQUINE or another medicine to prevent malaria while you are pregnant.

- **Breast feeding.** MEFLOQUINE can pass through your milk and may harm the baby. Therefore, ask your prescriber whether you will need to stop breast feeding or use another medicine.

**- Liver problems.**

**Tell your prescriber about all the medicines you take, including prescription and non-prescription medicines, vitamins, and herbal supplements.** This includes telling your doctor if you are taking anti-seizure medications such as valproic acid, carbamazepine, phenobarbital, and phenytoin. Some medicines may give you a higher chance of having serious side effects from MEFLOQUINE.

**How should I Take MEFLOQUINE?**

**Take MEFLOQUINE exactly as prescribed. If you are an adult or pediatric patient weighing 45 kg (99 pounds) or less, your prescriber will tell you the correct dose based on your weight.** There is limited information on the use of MEFLOQUINE in children less than 3 months old or weighing less than 5 kg.

**To Prevent Malaria**

• For adults and pediatric patients weighing over 45 kg, take 1 tablet of MEFLOQUINE at least 1 week before you travel to a malaria area (or 2 to 3 weeks before you travel to a malaria area, if instructed by your prescriber). This starts the prevention and also helps you see how MEFLOQUINE affects you and the other medicines you take. **Take 1 MEFLOQUINE tablet once a week,** on the same day each week, while in a malaria area.

• **Continue taking MEFLOQUINE for 4 weeks after returning from a malaria area.** If you cannot continue taking MEFLOQUINE due to side effects or for other reasons, contact your prescriber.

• Take MEFLOQUINE just after a meal and with at least 1 cup (8 ounces) of water.
• If you miss taking a dose, take it as soon as you realize you have forgotten, and then take each remaining dose according to the dosage schedule, counting from the day that you took the missed dose.

• For children, MEFLOQUINE can be given with water or crushed and mixed with water or sugar water. The prescriber will tell you the correct dose for children based on the child's weight.

• If you are told by a doctor or other health care provider to stop taking MEFLOQUINE due to side effects or for other reasons, it will be necessary to take another malaria medicine. You must 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 don't have access to a doctor or other health care provider or to another medicine besides MEFLOQUINE and have to stop taking it, leave the malaria area. However, be aware that leaving the malaria area may not protect you from getting malaria. You still need to take a malaria prevention medicine.**

**What should I do in case of an overdose?**

• If you take too much MEFLOQUINE, contact your doctor, regional Poison Control Centre or nearest hospital emergency immediately.

**What should I avoid while taking MEFLOQUINE?**

• **Halofantrine (marketed under various brand names),** a medicine used to treat malaria. Taking both of these medications together, or taking halofantrine within 15 weeks after the last dose of MEFLOQUINE, can cause serious heart problems that can cause death.

• **Ketoconazole,** a medicine used to treat fungal infections. Taking both of these medications together, or taking ketoconazole within 15 weeks after the last dose of MEFLOQUINE, can cause serious heart problems that can cause death.

• **Do not become pregnant. Women should use effective birth control while taking MEFLOQUINE.**

• **Quinine, quinidine, or chloroquine (other medicines used to treat malaria).** Taking these medicines with MEFLOQUINE could cause changes in your heart rate or increase the risk of seizures.

• **Alcohol.** It is best to avoid alcoholic drinks during treatment with MEFLOQUINE.

In addition:

• **Be careful driving or in other activities** needing alertness and careful movements (fine motor coordination). MEFLOQUINE can cause dizziness or vertigo or loss of balance, even after you stop taking it.

• **Be aware that certain vaccines may not work if given while you are taking MEFLOQUINE.**

Your prescriber may want you to finish taking your vaccines at least 3 days before starting MEFLOQUINE.

**What are the possible side effects of MEFLOQUINE?**

MEFLOQUINE, like all medicines, may cause side effects in some patients. The most frequently reported side effects with MEFLOQUINE when used for prevention of malaria include nausea, vomiting, diarrhea, dizziness, difficulty sleeping, and bad dreams. These are usually mild and do not cause people to stop taking the medicine.

In a small number of patients it has been reported that dizziness or vertigo and loss of balance may continue for months after discontinuation of the drug.

MEFLOQUINE may cause serious mental problems in some patients (See “What is the most important information I should know about MEFLOQUINE?”).

MEFLOQUINE may affect your liver and your eyes if you take it for a long time. Your prescriber will tell you if you should have your eyes and liver checked while taking MEFLOQUINE.

**What else should I know about preventing malaria?**

• **Find out whether you need malaria prevention.** Before you travel, talk with your prescriber about your travel plans to determine whether you need to take medicine to prevent malaria. Even in those countries where malaria is present, there may be areas of the country that are free of malaria. In general, malaria is more common in rural (country) areas than in big cities, and it is more common during rainy seasons, when mosquitoes are most common. You can get information about the areas of the world where malaria occurs from Health Canada and from local authorities in the countries you visit. If possible, plan your travel to reduce the risk of malaria.

• **Take medicine to prevent malaria infection.** Without malaria prevention medicine, you have a higher risk of getting malaria. Malaria starts with flu-like symptoms, such as chills, fever, muscle pains, and headaches. However, malaria can make you very sick or cause death if you don’t seek medical help immediately. These symptoms may disappear for a while, and you may think you are well. But, the symptoms return later and then it may be too late for successful treatment.

Malaria can cause confusion, coma, and seizures. It can cause kidney failure, breathing problems, and severe damage to red blood cells. However, malaria can be easily

diagnosed with a blood test, and if caught in time, can be effectively treated.

**If you get flu-like symptoms (chills, fever, muscle pains, or headaches) after you return from a malaria area,** get medical help right away and tell your health care provider that you may have been exposed to malaria.

People who have lived for many years in areas with malaria may have some immunity to malaria (they do not get it as easily) and may not take malaria prevention medicine. This does not mean that you don't need to take malaria prevention medicine.

• **Protect against mosquito bites.** Medicines do not always completely prevent your catching malaria from mosquito bites. So protect yourself very well against mosquitoes. Cover your skin with long sleeves and long pants, and use mosquito repellent and bed nets while in malaria areas. Ask your prescriber for other ways to protect yourself.

**General information about the safe and effective use of MEFLOQUINE**

Medicines are sometimes prescribed for conditions not listed in Information for the Patient guides. If you have any concerns about MEFLOQUINE, ask your prescriber. This Information for the Patient guide contains certain important information for travellers visiting areas with malaria. Your prescriber or pharmacist can give you information about MEFLOQUINE that was written for health care professionals. Do not use MEFLOQUINE for a condition for which it was not prescribed.

Do not share MEFLOQUINE with other people.

Information Wallet Card to carry when you are taking MEFLOQUINE.

MEFLOQUINE (mefloquine hydrochloride) Tablets – For Prevention of Malaria

You need to take malaria prevention medicine before you travel to a malaria area, while there, and after you leave a malaria area. If taking correctly, MEFLOQUINE is effective at preventing malaria, but like all medications, it may produce side effects in some patients. If you use MEFLOQUINE to prevent malaria and you develop a sudden onset of unexplained anxiety, depression, restlessness or irritability, or confusion (possible signs of more serious mental problems), or you develop other serious side effects, including a persistently abnormal heart beat or palpitations, contact a doctor or other health care provider. It may be necessary to stop taking MEFLOQUINE and use another malaria prevention medicine instead . If you can't get another medicine, leave the malaria area. However, be aware that leaving the malaria area may not protect you from getting malaria. You still need to take a malaria prevention medicine. Other medicines approved in Canada for malaria prevention include: doxycycline, atovaquone/proguanil, hydroxychloroquine, and chloroquine. Not all malaria medicines work equally well in malaria areas.

Please read the Information for the Patient guide for additional information on MEFLOQUINE.

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