

Patient information leaflet

MEFLY 250

Mefloquine Hydrochloride Tablets USP

Please read this leaflet carefully before you start to take your medicine. If you have any questions or are not sure about anything, ask your doctor or pharmacist.

In this leaflet you will find

1. What is MEFLY 250?
2. Before taking MEFLY 250
3. How to take this medicine
4. Possible side effects
5. How to store
6. Other information

1. What is MEFLY 250?

MEFLY 250 is an antimalarial drug containing Mefloquine hydrochloride 250 mg as an active pharmaceutical ingredient. This medicine is used to treat malaria and to help prevent you from catching malaria.

Malaria is a life threatening disease and a major health risk for travellers visiting tropical countries.

It occurs when small parasites are passed from one person to another by the bites of certain mosquitoes. MEFLY 250 is especially useful if you are travelling to countries where there is a type of malaria which is particularly difficult to treat. No single medicine is effective against all malaria parasites. The choice of a particular medicine depends on the sensitivity of the malaria parasites found in the area to be visited. Your doctor will advise you whether MEFLY 250 is suitable for the area to which you wish to go.

2. Before taking MEFLY 250

Do not take MEFLY 250, if you have

1. A history of psychiatric illness, mental complaints or severe changes of mood (such as depression), or you suffer from, or have ever suffered from fits. If you do, you should not take MEFLY 250 for prevention of malaria. Your doctor will assess whether MEFLY 250 is suitable for treatment of malaria.
2. Severe liver problems.
3. If you are allergic to MEFLY 250, any of the ingredients it contains or to similar medicines such as quinine, quinidine or chloroquine.

ny of the above applies to you, make sure your doctor knows, so that your doctor can prescribe a different medicine for treatment or prevention of malaria.

Also, consult your doctor immediately if you are already being treated with Halofantrine, or you have been prescribed a course of Halofantrine. Halofantrine (which is used to treat malaria) and MEFLY 250 taken at the same time can slow the heartbeat to a dangerous level. Therefore, to help avoid the possibility of a dangerous alteration in heart rhythm, you must not take Halofantrine if you are already taking, or have taken MEFLY 250 within the last 15 weeks.

Take special care while taking MEFLY 250

Make sure your doctor knows if you:

- Suffer from epilepsy.
- Have heart trouble, especially changes in heart rhythm.
- Have kidney problems.
- Have been told by a doctor that you have intolerance to some sugars, such as lactose.
- Have previously contracted malaria even though you were taking MEFLY 250 tablets for malaria prevention.
- If you are a woman of child-bearing age, you should take reliable contraceptive precautions whilst you are taking MEFLY 250, and for 3 months after the last dose.

Taking other medicines

Before starting treatment, make sure your doctor knows if you are taking other medicines (including those you have obtained without a prescription).

It is very important that you ask your doctor for advice if you are taking:

- Other related medicines such as quinine, quinidine, or chloroquine, used to treat or to prevent malaria.
- Medicines for any heart trouble, or high blood pressure, such as β -blocking agents, calcium channel blockers
- Medicines for blood clotting disorders or diabetes, as your doctor may wish to monitor you before you travel

- Antihistamines for allergies
- Medicines used to treat epilepsy, such as sodium valproate, carbamazepine, phenobarbital, phenytoin
- Medicines for some mental problems (psychiatric disorders) such as tricyclic anti-depressants or phenothiazines
- Ketoconazole (used to treat fungal infections) – you should also ask your doctor for advice before taking ketoconazole within 15 weeks after taking MEFLY 250

- Rifampicin (used to treat bacterial infections).

If you need an oral vaccine to help prevent you from catching typhoid, you should arrange to receive it at least 3 days before you need to start taking MEFLY 250. Otherwise, MEFLY 250 may stop the vaccine from working properly.

Pregnancy and breast-feeding

Pregnant women should not normally take these tablets.

It is important to tell your doctor if you are pregnant or think you could be pregnant, as she or he may decide that you should not use this medicine.

Women of child bearing age are advised to use adequate contraception whilst taking MEFLY 250 to prevent them from catching malaria and for 3 months after the last dose.

It is recommended that you do not breast-feed while you are taking these tablets.

Effects on the ability to drive and use machinery

MEFLY 250 can cause dizziness and loss of balance, and these effects may continue for some months after taking MEFLY 250 in a small number of patients. Sleepiness, fainting and fits have occurred occasionally. Patients who have been treated for malaria with MEFLY 250 should avoid driving operating machinery, piloting an aircraft or deep sea diving and tasks requiring fine co-ordination (accurate small movements) and spatial awareness (being aware of distances) during treatment and for at least 3 weeks afterwards.

3. How to take this medicine

Follow all directions given to you by your doctor or pharmacist.

Take the tablets with plenty of water, and preferably with or after food.

Swallow the tablets whole, do not suck or chew them.

Malaria prevention

Please read the following section if you are taking MEFLY 250 to help prevent you from catching malaria.

Important

- The tablets should be taken once weekly, always on the same day.
- You should start taking the tablets at least 1 week and up to 2 - 3 weeks before departure.
- You should continue taking the tablets throughout your stay and for 4 weeks after your return.
- The full course of tablets is at least 6 weeks, depending on your length of stay.
- For effective prevention you must take the full course of tablets.
- No anti-malarial tablets can be 100% guaranteed to work. There is a chance you could still get malaria during or after taking medicine to prevent it. If you develop a fever or flu-like symptoms during your travels or within 2 to 3 months after you leave the malarious area, check with a doctor immediately.

Adult dose:

An example of the recommended dose for a 2-week stay in an area where malaria is present is given below.

	Before Travel	During Travel		On your return	
Week number	at least 1 week	2	3	4	5
					6
					7
Dose	1 tablet weekly	1	1	1	1
					1
					1

A pack of 8 tablets is enough to help prevent you from catching malaria if you are staying for 3 weeks in an area where malaria is present and if you start

taking the tablets 1 week before departure. If your stay is longer than 3 weeks or if your doctor has advised that you should start taking your tablets 2 to 3 weeks before departure, you will need a second pack.

Adults weighing less than 45 kg should take the children's dose (see below).

Whether you are an adult or a child you should not take the tablets for more than 12 months.

Children's dose:

The tablets are not recommended for children under 3 months of age, i.e., those who weigh less than 5 kg (11 lbs). For children over this weight, the dose is shown in the table below. The tablets can be divided by breaking along the score lines. As in adults, the dose should be taken once weekly on the same day, and continued for 4 weeks after return.

Weight	Age (Approx.)	Dose
5-19 kg (11-42 lbs)	3 months - 5 years	1/4 Tablet
20-30 kg (44-66 lbs)	6-8 years	1/2 Tablet
31-45 kg (68-99 lbs)	9-14 years	3/4 Tablet

Malaria treatment

Please read the following section if you are taking the tablets to treat malaria. Your doctor will tell you how much medicine you need to take. This will depend on your weight and whether you have been living in a malarious area. Normally, you should not receive more than 6 tablets in total. You may be advised to split the total dose into 2 or 3 smaller doses, 6 - 8 hours apart, to reduce the likelihood or severity of unwanted effects.

If you take more tablets than you should, either for prevention or treatment

If you take too many tablets or someone else accidentally takes your medicine, contact your doctor, pharmacist or nearest hospital immediately.

If you forget to take your medicine, either for prevention or treatment

If you miss a dose, take it as soon as possible. If it is nearly time for your next dose, skip the missed dose and carry on as before. Do not take a double dose.

4. Possible side effects

Most people do not experience problems (unwanted effects) whilst taking MEFLY 250. However, if you develop any of the following potentially serious, symptoms, you should consult a doctor immediately, before taking your next dose.

- Severe allergic reaction (anaphylaxis) with symptoms such as difficulty in breathing, swollen tongue, itching and severe rash.
- Unusual changes in your mood or behaviour, including: feeling worried or anxious, feeling depressed, feeling that people are against you, crying or wanting to cry for no reason, restlessness, new or worsening feelings of anger (aggression), forgetfulness, agitation, confusion, panic attacks, seeing or hearing things that aren't really there (hallucinations), feeling that you want to kill yourself.
- Fits.
- Severe changes in heartbeat, including pounding, racing or skipped beats (palpitations).
- Severe changes in texture and appearance of the skin, especially if it affects your mouth and eyes.
- Inflammation of the lungs (pneumonitis), which may cause fever or chills, cough, breathlessness and chest pain.
- Severe problems with your liver which might be demonstrated by a transient increase in your liver enzymes shown by blood tests or other symptoms such as a tender, firm or possible enlarged liver, jaundice (yellowing of skin/eyes), dark urine, light coloured stools and generalised itchiness.

If you experience any other symptoms that worry you and you think that they may be due to the tablets, please seek medical advice as soon as possible, and before taking your next tablet. If necessary, the doctor may advise you to stop taking MEFLY 250 and take a different anti-malarial medicine.

MEFLY 250 can stay in the body for a long time after taking the last dose and therefore some unwanted effects may occur or last for more than several weeks.

If you are being treated for malaria, any unwanted effects of treatment may be similar to some of the symptoms of malaria itself.

Other side effects which have been reported in patients being treated with MEFLY 250 are listed below.

Very common (may affect more than 1 in 10 patients) - abnormal dreams, insomnia

Common (may affect more than 1 in 100 patients but less than 1 in 10 patients) – anxiety, depression, dizziness, headache, problems with your vision, vertigo (a feeling of moving when you are still), feeling or actually being sick, diarrhoea, stomach ache, skin rash.

Not known (the frequency cannot be estimated) – abnormal blood test results showing a decrease or an increase in WBC, a decrease in RBC or platelets, symptoms may include painful mouth or throat ulcers, fever, chills, bruises on the skin, nosebleeds, bleeding in the stomach or vaginal bleeding, Decreased appetite. Unusual changes in your mood or behaviour, including: feeling worried or anxious, feeling depressed, feeling that people are against you, crying or wanting to cry for no reason, restlessness, new or worsening feelings of anger (aggression), forgetfulness, agitation, confusion, panic attacks, seeing or hearing things that aren't really there (hallucinations) feeling that you want to kill yourself. Loss of balance, sleepiness, fits, fainting, “pins and needles”, weakness, new or worsening clumsiness or unsteadiness on your feet, or shaking of the hands and fingers, changes to your hearing including ringing in the ears or difficulty in hearing, changes to blood pressure or heart rate, palpitations (pounding or racing of your heart beat), hot flushes, breathlessness, inflammation of the lungs (pneumonitis) which may cause fever or chills, cough, indigestion. Changes to your liver function: jaundice, yellowing of the eyes, dark urine, light coloured stools, itchiness. Rash, changes in the texture or appearance of your skin (skin lesions), hair loss, sweating, muscle weakness, muscle cramps, joint pains, muscle pains, chest pain, tiredness, fever or chills.

Whilst taking this medicine, if you experience these or any other symptoms that concern you, tell your doctor.

5. How to store

The tablets should be stored in a dry place.

Store Below 30°C & store in original package. Sensitive to moisture.

Keep this medicine out of the reach of children. Return any leftover medicine to your pharmacist. Only keep it if your doctor tells you to. Remember this medicine is for you. Only a doctor can prescribe it for you. Never give it to others. It may harm them, even if their symptoms are the same as yours. The medicine must not be used after the date (EXP) printed on the pack.

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