

Package leaflet: Information for the patient

Mefloquine 250 mg Tablets

Mefloquine

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor, pharmacist or nurse.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What Mefloquine is and what it is used for
2. What you need to know before you take Mefloquine
3. How to take Mefloquine
4. Possible side effects
5. How to store Mefloquine
6. Contents of the pack and other information

1. What Mefloquine is and what it is used for

Mefloquine tablets contain the active ingredient mefloquine. Mefloquine 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. Mefloquine 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 Mefloquine is suitable for the area to which you wish to go.

To help minimise your chance of catching the disease and to protect you from possible serious side effects it is important that you read this leaflet carefully. Ask your doctor to explain anything you do not understand.

2. What you need to know before you take Mefloquine

Do not take Mefloquine if you have or have previously experienced:

- an allergy to mefloquine or any of the other ingredients of this medicine (see section 6 “Contents of the pack and other information”) or to similar medicines such as quinine or quinidine
- depression, thoughts about suicide and self-endangering behaviour
- any other mental problem, including anxiety disorder, schizophrenia or psychosis (losing touch with reality)
- fits (seizures or convulsions)
- severe liver problems
- blackwater fever (a complication of malaria that affects the blood and kidneys)

If any of the above applies to you, make sure your doctor knows, so that your doctor can prescribe a different medicine for prevention or treatment 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 Mefloquine 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 Mefloquine within the last 15 weeks.

Warnings and precautions

Mefloquine may cause serious mental problems in some people. Tell your doctor immediately if you experience any of the following while taking Mefloquine:

- suicidal thoughts
- self-endangering behaviour
- severe anxiety
- feelings of mistrust towards others (paranoia)
- seeing or hearing things that are not there (hallucinations)
- nightmares / abnormal dreams
- insomnia
- depression
- feeling restless
- unusual behaviour
- feeling confused

Please seek medical help immediately if you experience serious mental problems while taking Mefloquine. Mefloquine should be stopped immediately and replaced with another medicine to prevent malaria.

Talk to your doctor, pharmacist, or nurse before taking Mefloquine if you have:

- epilepsy
- fits (seizures or convulsions)
- heart problems, especially changes in heart rhythm
- liver or kidney problems
- eye problems (e.g. loss of fine detail, colours seem faded, sudden loss of vision, poor vision at night)
- blood or lymphatic disorder (abnormal blood test showing a decrease or an increase in white blood cells, a decrease in red blood cells or platelets)
- neuropathy with signs of e.g. pins and needles, weakness, numbness, new or worsening clumsiness or unsteadiness on your feet, or shaking of the hands and fingers
- inflammation of the lungs, also known as pneumonitis. This is a serious, potentially life-threatening allergic reaction in the lungs which may cause fever, chills, cough, shortness of breath or chest pain.
- previously contracted malaria even though you were taking Mefloquine tablets for malaria prevention
- experienced a mild to serious potential life threatening allergic reaction to Mefloquine or any of its ingredients
- low blood glucose due to a pre-existing condition called congenital hyperinsulinemic hypoglycaemia

Some side effects may occur after you have stopped taking Mefloquine. In a small number of patients it has been shown that depression, dizziness or vertigo and loss of balance may persist for months or longer, even after you have stopped taking Mefloquine.

Children

Experience with Mefloquine in infants less than 3 months old or weighing less than 5 kg is limited.

Other medicines and Mefloquine

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

Tell your doctor, pharmacist, or nurse if you are taking, have recently taken or might take any other medicines including:

- halofantrine, or you have been prescribed a course of halofantrine (see section 2 “Things you should know before taking Mefloquine”)
- 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
- antihistamines for allergies
- medicines for some mental problems (psychiatric disorders). Anti-depressants such as tricyclic anti-depressants, selective serotonin reuptake inhibitors (SSRIs), bupropion or anti-psychotics such as phenothiazines.
- medicines used to treat epilepsy, such as sodium valproate, carbamazepine, phenobarbital, phenytoin
- ketoconazole (used to treat fungal infections) – you should also ask your doctor for advice before taking ketoconazole within 15 weeks after taking Mefloquine
- antibiotics used to treat bacterial infections for example rifampicin, penicillins, cephalosporins
- efavirenz (used to treat HIV infections)
- tramadol (used to treat severe pain)
- medicines for blood clotting disorders or diabetes, as your doctor may wish to monitor you before you travel

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 Mefloquine. Otherwise, Mefloquine may stop the vaccine from working properly.

Pregnancy and breast-feeding

Pregnant women should not normally take these tablets.

Due to the seriousness of malaria during pregnancy, it is recommended that you should not travel to an area where you could become infected with malaria if you are pregnant, think that you may be pregnant, or if you are planning to have a baby.

Mefloquine should be avoided by women who are breast-feeding.

If you are pregnant or breast-feeding, think that you may be pregnant, or planning to have a baby, ask your doctor for advice before taking this medicine, as he or she may decide that you should not use this medicine.

Driving and using machines

Take special care if you perform activities requiring alertness and coordination (accurate small movements) and spatial awareness (being aware of distances) such as driving, piloting an aircraft, operating machinery, and deep-sea diving as Mefloquine can cause dizziness, loss of balance and mental problems. If you are in any doubt about whether you can do a particular activity, talk to your doctor.

In a small number of patients it has been shown that dizziness, vertigo and loss of balance may persist for months or longer after stopping Mefloquine.

Mefloquine contains lactose

If you have been told by your doctor that you have an intolerance to some sugars, such as lactose or galactose, you should not take Mefloquine. Contact your doctor before taking this medicinal product.

3. How to take Mefloquine

Always take this medicine exactly as your doctor has told you. Check with your doctor if you are not sure. The advice you are given will depend on whether you are taking the tablets for prevention or treatment of malaria. Take the tablets with plenty of water, and preferably after a meal. Swallow the tablets whole, do not suck or chew them.

Malaria prevention

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

Important

- Take the tablets once a week, always on the same day.
- Take the 1st dose 10 days before you leave: this is to make sure that Mefloquine is well tolerated. Take the 2nd dose 3 days before you leave.
- Continue taking the tablets on the same day of the week 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.

Adults and children over 45 kg body weight, dose:

One tablet weekly (always on the same day).

A pack of 8 tablets is enough to help prevent you from catching malaria if you are staying for 2 weeks in an area where malaria is present and you start taking the tablets at 10 days and 3 days before departure.

Adults weighing less than 45 kg (99 lbs) 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 (approx. 11 – 43 lbs)	3 months – 5 years	¼ tablet
20 – 30 kg (approx. 44 – 67 lbs)	6 – 8 years	½ tablet
31 – 45 kg (approx. 68 – 99 lbs)	9 – 14 years	¾ 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 side effects.

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

If you take too many tablets the likelihood and severity of the side effects as described in section 4 may increase. There are no specific antidotes.

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 Mefloquine, 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

Like all medicines, this medicine can cause side effects although not everybody gets them.

Mefloquine may cause serious mental problems in some people. Stop taking this medicine and contact your doctor immediately if you experience any of the following while taking Mefloquine:

Common (may affect up to 1 in 10 people):

- depression
- anxiety

Not known (frequency cannot be estimated from the available data):

- suicide
- attempted suicide
- suicidal thoughts
- self-endangering behaviour
- losing touch with reality (psychosis)
- feelings of mistrust towards others (paranoia)
- panic attacks
- unusual behaviour
- feeling confused
- seeing or hearing things that are not there (hallucinations)
- aggression
- agitation
- feeling restless
- unusual changes in your mood
- disturbance in attention

Please seek medical help immediately if you experience serious mental problems while taking Mefloquine. Mefloquine should be stopped immediately and replaced with another medicine to prevent malaria.

If you develop any of the following potentially serious symptoms, you should STOP taking this medicine and also consult a doctor immediately.

Not known (frequency cannot be estimated from the available data):

- a mild to serious potential life-threatening allergic reaction (anaphylaxis) to Mefloquine or any of its ingredients with symptoms such as difficulty in breathing, swollen tongue, itching and severe rash
- severe changes in texture and appearance of the skin, especially serious blistering and peeling that affects the mouth, eyes and genitals (Stevens Johnson syndrome)
- fits (seizures or convulsions)
- heart problems e.g. severe changes in heartbeat, including pounding, racing or skipped beats (palpitations)
- inflammation of the lungs, also known as pneumonitis. This is a serious, potentially life-threatening allergic reaction in the lungs which may cause fever, chills, cough, shortness of breath or chest pain.
- severe liver problems which might be demonstrated by a transient increase in your liver enzymes shown by blood tests or other symptoms such as tender, firm or possibly enlarged liver, jaundice (yellowing of skin/eyes), dark urine, light coloured stools and generalised itchiness

Other possible side effects

Very common (may affect more than 1 in 10 people):

- sleeping problems (sleepiness, unable to sleep, bad dreams)

Common (may affect up to 1 in 10 people):

- dizziness
- headache
- problems with your vision
- loss of balance (vertigo)
- feeling sick (nausea), being sick (vomiting)
- diarrhoea
- stomach ache (abdominal pain)

- itching

Not known (frequency cannot be estimated from the available data):

- abnormal blood test results showing a decrease or an increase in white blood cells, a decrease in red blood cells or platelets. Symptoms may include painful mouth or throat ulcers, fever, chills, bruises on the skin, nosebleeds, bleeding in the stomach or vaginal bleeding.
- kidney problems, failure or infection, causing impairment, cessation, infection, or blood in the urine. Symptoms may include abnormal blood tests (increased blood creatinine), feeling dehydrated, fatigue, swelling (oedema), shortness of breath, feeling or being sick, loss of appetite, or headache
- decreased appetite
- fainting
- neuropathy with signs of e.g. “pins and needles”, weakness, new or worsening clumsiness or unsteadiness on your feet, or shaking of the hands and fingers
- forgetfulness (sometimes lasting for more than 3 months)
- difficulties in talking
- difficulties with sense of smell and taste, eye movement, facial sensation and expression, hearing, balance, tasting, tongue movement, head-turning, and raising your shoulders
- cataract, dazzled in the evenings or other vision disturbances, blurred vision
- changes to your hearing including ringing in the ears or difficulty in hearing (sometimes prolonged), everyday sounds seeming too loud
- changes to blood pressure or heart rate
- hot flushes
- breathlessness, cough
- pancreas problems; symptoms may include stomach pain, nausea, vomiting, changes to blood pressure or heart rates and breathlessness
- indigestion
- rash
- hair loss
- sweating
- muscle weakness
- muscle cramps
- joint pains
- muscle pains
- oedema
- chest pain
- tiredness
- fever or chills

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

Some side effects may occur after you have stopped taking Mefloquine. In a small number of patients it has been shown that depression, dizziness or vertigo and loss of balance may persist for months or longer, even after you have stopped taking Mefloquine.

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist, or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme at: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Mefloquine

- Keep this medicine out of the sight and reach of children.
- Do not use this medicine after the expiry date which is printed on the carton and blister foil after (EXP). The expiry date refers to the last day of that month.
- Do not store above 30°C.
- Keep the blister in the outer carton in order to protect it from moisture.
- Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What Mefloquine contains

The active substance in Mefloquine is mefloquine. Mefloquine is an anti-malarial. Each tablet contains 250 mg of mefloquine (as mefloquine hydrochloride).

The other ingredients in Mefloquine tablets are poloxamer, microcrystalline cellulose, lactose monohydrate, maize starch, crospovidone, ammonium calcium alginate, talc, and magnesium stearate.

What Mefloquine looks like and contents of the pack

Appearance: The tablets are white to off-white, cross-scored, and imprinted with LA-RI-AM-CP on one face.

Pack size: The tablets are available in foil strips in packs of 8.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder

Neon Healthcare Limited
8 The Chase, John Tate Road
Hertford, SG13 7NN
United Kingdom

Manufacturer

CHEPLAPHARM Arzneimittel GmbH
Ziegelhof 23-24
17489 Greifswald
Germany

For information about this medicine, contact the medical information department via email: medinfo@neonhealthcare.com.

You can get more information on Mefloquine from your doctor, pharmacist or nurse.

It is essential that you follow the recommendations given for taking the tablets.

Other preventative actions you should take

If you are taking Mefloquine to prevent malaria, you should also take steps to avoid mosquito bites. Some information on how to avoid bites is given below. This is important as no medicine can be 100% guaranteed to protect you against malaria.

- Make sure you sleep in a room that is screened against mosquitoes or has full air conditioning, or that you use a mosquito net (preferably one that has been treated with an insect repellent) over the bed.

- Use insect repellents; ointments, lotions and sprays, to deter mosquitoes.
- In the evening, cover arms and legs with light-coloured, long-sleeved clothes and trousers, and use an insect repellent. Anklets are also available which have been treated with repellent.
- Vaporising electric “mats”, mosquito coils or tablets can be used at night-time around exposed areas of the body (ankles and feet).

This leaflet was last revised in March 2022.