

## Package Leaflet: Information for the user

**Lariam<sup>®</sup> 250 mg**

**Tablets**

Mefloquine

**Roche**

**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 or pharmacist.
- 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 or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

### What is in this leaflet

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

## 1. What Lariam is and what it is used for

Lariam Tablets contain the active ingredient mefloquine. They are 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. Lariam 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 Lariam 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 Lariam

### Do not take Lariam:

- if you are allergic to mefloquine or any of the other ingredients of this medicine (listed in section 6) or to similar medicines such as quinine, quinidine or chloroquine
- if you have depression, thoughts about suicide and self-endangering behaviour
- if you have any other mental problem, including anxiety disorder, schizophrenia or psychosis (losing touch with reality)
- if you have fits (seizures or convulsions)
- if you have severe liver problems
- if you have had 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 Lariam 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 Lariam within the last 15 weeks.

## **Warnings and precautions**

**Lariam may cause serious mental problems in some people. Please seek medical help immediately if you experience any of the following:**

- suicidal thoughts
- self-endangering behaviour
- severe anxiety

**Tell your doctor if you experience any of the following:**

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

**Talk to your doctor or pharmacist before taking Lariam if you:**

- suffer from epilepsy
- have fits (seizures or convulsions)
- have heart problems, especially changes in heart rhythm
- have liver or kidney problems
- have eye problems (eg loss of fine detail, colours seem faded, sudden loss of vision, poor vision at night)
- abnormal blood test showing a decrease or an increase in white blood cells or a decrease in red blood cells or platelets
- experience pins and needles, weakness, numbness, new or worsening clumsiness or unsteadiness on your feet, or shaking of the hands and fingers
- experience fever, chills, cough, shortness of breath or chest pain. These could be signs of inflammation of the lungs also known as pneumonitis
- have previously contracted malaria even though you were taking Lariam tablets for malaria prevention

If you are a woman of child-bearing age, you should take reliable contraceptive precautions whilst you are taking Lariam, and for 3 months after the last dose.

## **Children**

Experience with Lariam in babies less than 3 months old or weighing less than 5 kg is limited.

## **Other medicines and Lariam**

**Tell your doctor or pharmacist 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)
- 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 b-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 Lariam
- 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 Lariam. Otherwise, Lariam 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 he or she may decide that you should not use this medicine.

Women of child bearing age are advised to use adequate contraception whilst taking Lariam 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.

### **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 Lariam can cause dizziness, loss of balance and mental problems (see section 2).

In a small number of patients it has been shown that dizziness, vertigo and loss of balance may persist for months or longer after you have stopped taking Lariam.

### **Lariam contains lactose**

If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.

## **3. How to take Lariam**

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 Lariam 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.

<b>Weight</b>	<b>Age (approx.)</b>	<b>Dose</b>
5 – 19 kg (11 – 42 lbs)	3 months – 5 years	¼ tablet
20 – 30 kg (44 – 66 lbs)	6 – 8 years	½ tablet
31 – 45 kg (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 Lariam 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.

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 Lariam, 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.

### **Stop taking this medicine and contact your doctor immediately if you experience:**

- attempted suicide
- suicidal thoughts
- self-endangering behaviour
- allergic reaction (anaphylaxis) with symptoms such as difficulty in breathing, swollen tongue, itching and severe rash

- severe changes in texture and appearance of the skin, especially if it affects your mouth and eyes (Stevens Johnson syndrome)
- psychosis (losing touch with reality)
- severe anxiety
- depression
- panic attacks
- fits (seizures or convulsion)
- fever, chills, cough, shortness of breath or chest pain. These could be signs of inflammation of the lungs also known as pneumonitis
- 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
- Pins and needles, weakness, numbness, new or worsening clumsiness or unsteadiness on your feet, or shaking of the hands and fingers
- Painful mouth or throat ulcers, fever, chills, bruises on the skin, nosebleeds, bleeding in the stomach or vaginal bleeding. These could be signs of blood disorders

### **Talk to your doctor if you experience:**

- feelings of mistrust towards others (paranoia)
- seeing or hearing things that are not there (hallucinations)
- feeling restless
- unusual behaviour
- feeling confused
- unusual changes in your mood
- agitation
- new or worsening feeling of anger (aggression)
- disturbance in attention
- heart problems e.g. severe changes in heartbeat, including pounding, racing or skipped beats (palpitations)

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

### **Other side effects**

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

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

**Common** (may affect up to 1 in 10 patients):

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

**Frequency not known** (cannot be estimated from available data):

- decreased appetite, forgetfulness (sometimes lasting for more than 3 months), fainting
- difficulties in talking, cataract, blurred vision, dazzled in the evenings or other vision disturbances
- changes to your hearing including ringing in the ears or difficulty in hearing (sometimes prolonged)
- changes to blood pressure or heart rate, hot flushes, breathlessness, cough, indigestion, rash, hair loss, sweating, muscle weakness, muscle cramps, joint pains, muscle pains, oedema, chest pain, tiredness, fever or chills

Some side effects may occur after you have stopped taking Lariam. 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 Lariam.

### **Reporting of side effects**

If you get any side effects, talk to your doctor or pharmacist. 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](http://www.mhra.gov.uk/yellowcard)

By reporting side effects you can help provide more information on the safety of this medicine.

## 5. How to store Lariam

- 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 after (EXP).
- Do not store above 30°C
- Keep the blister in the outer carton in order to protect 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 Lariam contains

- the active substance is mefloquine. Each tablet contains 250 mg of mefloquine (as mefloquine hydrochloride).
- The other ingredients are poloxamer, microcrystalline cellulose, lactose, maize starch, crospovidone, ammonium calcium alginate, talc, magnesium stearate.

### What Lariam looks like and contents of the pack

**Appearance:** The tablets are white and are cross-scored.

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

### Marketing Authorisation Holder and Manufacturer responsible for batch release

Roche Products Limited  
6 Falcon Way  
Shire Park  
Welwyn Garden City  
AL7 1TW  
United Kingdom

You can get more information on Lariam from your doctor or pharmacist.

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

### Other preventative actions you should take

If you are taking Lariam 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 April 2014**