

## **Patient Leaflet: Information for the patient**

**Lariam® 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, 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 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. Lariam 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. 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 have or have previously experienced:**

- 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)
- an allergy to quinine, quinidine, Lariam or any of its ingredients (see section 6 “Contents of the pack and other information”)

**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. Tell your doctor immediately if you experience any of the following while taking Lariam:**

- 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
- depression
- feeling restless
- unusual behaviour
- feeling confused

**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.**

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

- epilepsy
- fits (seizures or convulsions)
- heart problems, especially changes in heart rhythm
- liver or kidney problems
- an intolerance to some milk sugars, such as lactose or galactose. If you have this you should not take Lariam.
- eye problems
- blood or lymphatic disorders (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, 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 or chills, cough, shortness of breath or chest pain.

- experienced a mild to serious potential life threatening allergic reaction to Lariam or any of its ingredients
- low blood glucose due to a pre-existing condition called congenital hyperinsulinemic hypoglycaemia
- previously contracted malaria even though you were taking Lariam tablets for malaria prevention

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.

### **Children**

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

### **Other medicines and Lariam**

Before taking Lariam, 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 “Do not take Lariam if you have or have previously experienced”).
- 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  $\beta$ -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 antipsychotics 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.

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.

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

If you are pregnant or breast-feeding, think that you may be pregnant, or are 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, cycling, and deep-sea diving as Lariam 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 Lariam.

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

Always take the tablets 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 1<sup>st</sup> dose of Lariam 10 days before you leave: this is to make sure that Lariam is well tolerated. Take the 2<sup>nd</sup> 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  | 3 months – 5 years | ¼ tablet |
| 20 – 30 kg | 6 – 8 years        | ½ tablet |
| 31 – 45 kg | 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. 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 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, Lariam can cause side effects, although not everybody gets them.

**Lariam 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 Lariam:**

**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 Lariam. Lariam should be stopped immediately and replaced with another medicine to prevent malaria.**

**If you develop any of the following potentially serious symptoms, you should 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 Lariam or any of its ingredients with symptoms such as difficulty in breathing, swollen tongue, itching and severe rash
- fits (seizures or convulsions)
- heart problems e.g. 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 (Stevens Johnson syndrome)
- inflammation of the lungs, also known as pneumonitis. This is a serious, potentially life-threatening allergic reaction in the lungs which may cause fever or chills, cough, breathlessness, 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 a tender, firm or possible 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) or actually 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 a decrease in or absence of urine production or blood in the urine. Symptoms may include abnormal blood tests (increase in blood creatinine), feeling dehydrated, fatigue, swelling, 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, glare or other vision disturbances, blurred vision
- changes to your hearing including ringing in the ears, 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
- swelling
- 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 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, pharmacist, or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly (see details below). By reporting side effects you can help provide more information on the safety of this medicine.

### **Ireland**

HPRA Pharmacovigilance

Earlsfort Terrace  
IRL - Dublin 2  
Tel: +353 1 6764971  
Fax: +353 1 6762517  
Website: [www.hpra.ie](http://www.hpra.ie)  
e-mail: [medsafety@hpra.ie](mailto:medsafety@hpra.ie)

## 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 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 Lariam contains

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

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

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

**Appearance:** The tablets are white to off-white, cross-scored, and imprinted with Roche on one face.

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

### Marketing Authorisation Holder

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

### Manufacturer

Roche Pharma AG  
Emil-Barell-Str. 1  
D-79639 Grenzach-Wyhlen  
Germany

You can get more information on Lariam 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 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 December 2015.**