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**PATIENT PACKAGE INSERT IN ACCORDANCE WITH THE PHARMACISTS' REGULATIONS (PREPARATIONS) - 1986**

The medicine is dispensed with a doctor's prescription only

# Lariam

## 250 mg

### Tablets



#### Composition:

Each tablet contains:

Mefloquine hydrochloride 274.09 mg (= Mefloquine base 250 mg)

\* For information on the inactive ingredients, see section 6 "Further Information".

#### Read this leaflet carefully in its entirety before using the medicine.

This leaflet contains concise information about the medicine. If you have further questions, refer to the doctor or pharmacist. Keep this leaflet; you may need to read it again.

This medicine has been prescribed to treat your ailment. Do not pass it on to others. It may harm them even if it seems to you that their ailment is similar.

#### IMPORTANT INFORMATION FOR YOUR REVIEW

- The dosage of the medicine changes in accordance with the objective of the treatment: whether for treating or for preventing malaria.
- The medicine contains lactose.

#### 1) WHAT IS THE MEDICINE INTENDED FOR?

##### Therapeutic activity:

For treatment and prevention of malaria resistant to other antimalarial preparations.

**Lariam** works by killing the parasites that may cause or have caused malaria.

**Therapeutic group:** Antimalarial preparations from the quinolones group.

Where and how can malaria be contracted?

Malaria is an infectious disease that is widespread in the tropical and subtropical areas of Africa, Latin America, Asia and countries around the Pacific Ocean. There are different forms of malaria, each of them caused by a specific parasite transmitted to humans by the bite of the Anopheles mosquito.

Precautions against malaria

The best way to protect yourself against malaria is to avoid mosquito bites. The mosquito that causes malaria mainly bites between dusk and dawn. Therefore, the following precautionary measures are recommended:

- during these hours, wear light-colored clothing that covers as much of your skin as possible.
- apply mosquito repellent to your uncovered skin and to your clothes.
- when sleeping in rooms that are not protected against mosquitoes, use an effective mosquito net, which should be well tucked under the mattress.
- smoke spirals, insect sprays and candles provide additional protection.

Symptoms of malaria

The symptoms of malaria may often be mild. However, malaria should be suspected if, after one week in a malarial area, you suffer from unexplained fever with or without other symptoms such as headache, aching limbs, weakness, shaking, chills, and sometimes diarrhea, vomiting and cough. These symptoms can easily be confused with influenza symptoms.

If these symptoms are due to the most dangerous form of malaria caused by the falciparum parasite, and they are not treated in time, severe organ damage, loss of consciousness and death can occur within a short period of time. The less dangerous forms of malaria, which are not life-threatening, can break out months or even years after the end of a stay in a malarial area.

Diagnosis and treatment of malaria

Early diagnosis is critical for successful treatment. Anyone suspected of having malaria should seek medical attention promptly and request that a blood sample be taken and examined microscopically for malaria parasites.

Most tourists or travelers will normally be able to receive medical attention. However, if medical attention is not readily available, the instructions for emergency treatment (stand-by treatment), which are detailed in section 3 of this leaflet can be followed.

Consult with the doctor about the need to carry 'stand-by treatment' on your trip. Medical advice should still be sought after administering stand-by treatment.

There are many different types of medicines used for the treatment and prevention of malaria.

The doctor may prescribe **Lariam** for another purpose.

Refer to the doctor if you have questions as to why you were prescribed **Lariam**.

The medicine **Lariam** is not addictive.

#### 2) BEFORE USING THE MEDICINE

##### Do not use the medicine:

- if you have a known sensitivity to the active ingredient (mefloquine) or to similar compounds (e.g., quinine and quinidine) or to any of the medicine's ingredients
  - as a preventive treatment if you have a history of convulsions/seizures (epileptic fits)
  - as a preventive treatment if you are depressed or if you have a history of a severe mental illness
- Some people who take **Lariam** may suddenly experience serious mental problems. Symptoms of serious mental problems may include:
- severe anxiety
  - hallucinations
  - depression
  - feeling restless
  - unusual behavior
  - feeling confused
- if you have had an allergic reaction to any of the inactive ingredients listed in section 6. Some of the symptoms of an allergic reaction may include:
    - shortness of breath
    - wheezing or difficulty breathing
    - swelling of the face, lips, tongue or other parts of the body
    - rash, itching or hives on the skin
  - if the package of the medicine is torn or shows signs of tampering
  - if the expiry date printed on the package has passed. If you take this medicine after the expiry date has passed, it may not work properly

##### Special warnings regarding use of the medicine

Tell the doctor:

- if you are pregnant or plan to become pregnant. If there is a need to take **Lariam** during pregnancy, particularly during the first three months of pregnancy, the doctor will discuss with you the risks and benefits of taking **Lariam**.

- if you are breastfeeding or plan to breastfeed. **Lariam** passes into breast milk, therefore, the doctor will discuss the risks and benefits of taking **Lariam** if you are breastfeeding.
- if you are suffering, or have suffered in the past, from any other health problems, especially the following: epilepsy or convulsions, liver disease, malaria.
- if you suffer from eye problems. Cases of optic neuropathy and retinal disturbances have been reported during treatment with **Lariam**. In some cases, recovery from such an event is very slow; however there have also been reports of permanent complications.
- if you have recently had a vaccination.
- if you are allergic to any other medicines, food, food colorings or preservatives.

If you have not told the doctor about any of the above, do so before you start taking **Lariam**.

#### Lariam and other medicines

If you are taking, or have recently taken, other medicines, including non-prescription medicines and nutritional supplements, tell the doctor or pharmacist. Particularly inform the doctor or pharmacist if you are taking or have recently taken:

- talofantrine, a medicine used to treat malaria; do not take this medicine during treatment with **Lariam** or for 15 weeks after taking the last dose of **Lariam**
- ketoconazole, an antifungal medicine
- quinine, a medicine used to treat malaria or cramps
- quinidine, a medicine used to treat heart problems

**Do not use the aforementioned medicines with Lariam or after treatment with Lariam. It may cause serious heart problems.**

Other medicines that may affect the activity of **Lariam**:

- chloroquine, a medicine used to treat or prevent malaria
- rifampicin, a medicine used to treat infections
- medicines used to treat epileptic fits, such as: valproic acid, carbamazepine, phenobarbital and phenytoin
- some medicines used to treat or prevent irregular heartbeat
- medicines used to treat high blood pressure (e.g., a group of medicines called beta-blockers)
- some medicines used to treat depression and other mental disorders
- some antihistamine medicines
- medicines used to lower blood sugar (to treat diabetes)
- medicines used to prevent blood clots
- 'live' vaccines. Complete a vaccination with a 'live' vaccine at least three days before receiving the first dose of **Lariam**. Consult with the doctor if you are not sure which vaccines are considered 'live'.

The aforementioned medicines may be affected by **Lariam**, or may affect the activity of **Lariam**. You may need to take different amounts of your medicine, or you may need to take different medicines. Consult with the doctor.

The doctor and pharmacist have more information about medicines to be careful with or that should be avoided while being treated with **Lariam**.

**Consult with the doctor or pharmacist if you are not sure about this list of medicines.**

#### Children

Experience with use of **Lariam** in infants less than 3 months old or weighing less than 5 kg is limited. In these cases, consult the doctor regarding use of **Lariam**.

#### Pregnancy and breastfeeding

If you are pregnant or breastfeeding or think you may be pregnant or are planning on becoming pregnant, consult with the doctor before using this medicine.

Women of child-bearing age should use effective contraceptives during the entire course of treatment and for at least three additional months after taking the last dose.

#### Driving, use of machinery and drinking alcohol

Use of this medicine may impair alertness, cause dizziness and loss of balance and therefore requires that caution be exercised when driving a car, operating machinery and when engaging in any other activity that can be dangerous in such conditions.

Drinking alcohol during the course of treatment with the medicine may increase these effects.

These effects may continue for several weeks after terminating treatment with the medicine.

#### Important information regarding some of the ingredients of the medicine

The preparation contains lactose and may cause an allergic reaction among people sensitive to lactose.

#### 3) HOW SHOULD YOU USE THE MEDICINE?

Always use according to the doctor's instructions.

Check with the doctor or pharmacist if you are uncertain.

##### Recommended dosage

The dosage and treatment regimen will be determined by the doctor only. Do not exceed the recommended dose.

The doctor will tell you how many **Lariam** tablets to take and when to take them.

##### Recommended dosage for prevention of malaria:

The usual dose for people weighing 45 kg or more is one **Lariam** tablet once a week. People weighing less than 45 kg may need to have their weekly dose reduced. The doctor will tell you what dose is right for you.

Take the first tablet one week before you arrive in a malarial area. Continue to take one tablet each week on the same day, while you are in a malarial area, and each week for 4 weeks after you have left a malarial area.

If you are unable to take **Lariam** one week before entering a malarial area, the doctor may give you different dosage instructions.

##### Recommended dosage for treatment of malaria (including stand-by treatment):

The usual dose for people weighing between 45-60 kg is five **Lariam** tablets. Three tablets should be taken initially and the remaining 2 tablets should be taken 6-8 hours later.

The usual dose for people weighing more than 60 kg is six **Lariam** tablets. Three tablets should be taken initially, a further two tablets 6-8 hours later and the remaining one tablet, 6-8 hours after that.

People weighing less than 45 kg may need to have their dose reduced. The doctor will tell you which dose is right for you.

If you have previously been in a malarial area, you may require a lower dose of **Lariam**. Refer to the doctor for advice.

If you vomit less than 30 minutes after taking a dose of **Lariam**, you should repeat this dose.

If you vomit 30-60 minutes after taking a dose, take an additional half dose, e.g., if you took 3 tablets and vomited, you should take an additional 1.5 tablets.

##### Dosage for children:

According to the doctor's instructions. Do not exceed the recommended dose.

##### Directions for use of the medicine

Swallow the tablet whole with at least one glass of water. The medicine has a bitter taste and stings a bit.

It is preferable to take the medicine after a meal.

The tablets may be crushed or suspended in a small amount of water, milk or other drink for administration to young children and people who have difficulty swallowing the tablets whole.

For prevention of malaria, take the medicine once a week, always on the same day of the week after a meal.

##### Duration of treatment

Continue taking **Lariam** until the doctor tells you to stop.

The length of therapy depends on whether **Lariam** is used for treatment or prevention of malaria.

**If you accidentally take too high a dosage**, contact the doctor immediately! You may experience more side effects and need immediate medical attention.

If you took an overdose, or if a child has accidentally swallowed the medicine, immediately refer to a doctor or proceed to a hospital emergency room and bring the package of this medicine with you.

##### If you forget to take the medicine

If you forgot to take the second or third dose of the medicine during the treatment of malaria, take the dose as soon as you remember and contact the doctor.

If you are not sure what to do, consult with the doctor or pharmacist.

For prevention of malaria, take the medicine once a week, always on the same day of the week. If you forget to take the dose, take the dose as soon as you remember and continue taking the dose once a week.

Adhere to the treatment regimen as recommended by the doctor.

##### How can you contribute to the success of the treatment?

Inform the doctors, dentists and pharmacists who treat you that you are taking **Lariam**.

Tell the doctor if, for any reason, you have not taken your medicine as prescribed. Otherwise, the doctor may think that it was not effective and change your treatment unnecessarily.

If you are taking **Lariam** for the treatment of malaria, inform the doctor if you feel the tablets are not helping your condition.

If you are taking **Lariam** for the treatment of malaria, be sure to keep all of your appointments with the doctor so that your condition can be monitored.

Make sure that you are not going to run out of **Lariam** tablets on a weekend or on holidays.

Do not use **Lariam** to treat other complaints, unless the doctor has instructed you to do so.

Do not take medicines in the dark! Check the label and the dose each time you take medicine. Wear glasses if you need them.

If you have further questions regarding use of this medicine, consult a doctor or pharmacist.

#### 4) SIDE EFFECTS

As with any medicine, use of **Lariam** may cause side effects in some users. Do not be alarmed when reading the list of side effects. You may not suffer from any of them.

You may need medical attention if you suffer from some of the side effects.

When **Lariam** is used to treat malaria, the side effects may occur more often than when it is used to prevent malaria.

If you are taking **Lariam** for the treatment of malaria, you may not be able to distinguish between the symptoms of malaria and the side effects of **Lariam**.

**Refer to a doctor or proceed to an emergency room as soon as possible if you suffer from one of the following side effects:**

- abnormal or strange dreams, which may continue after **Lariam** treatment is stopped
- change in mood, such as: bipolar disorder, depression (may last for months and longer), restlessness, confusion, agitation, aggression, feeling anxious or nervous, irrational beliefs (delusions), depersonalization disorder, hallucinations, suicidal thoughts or panic attacks, which may also occur after **Lariam** treatment is stopped
- seizures (fits), convulsions
- irregular or racing heartbeat, chest pain
- light-headedness
- fatigue, flushing of the face and neck
- loss of consciousness
- eye problems, such as blurred vision or eye pain
- hearing disturbances
- tremor
- fever, sweating, chills
- muscle pain, cramps or weakness
- joint pain
- difficulty breathing, shortness of breath, chest tightness, coughing or wheezing
- tingling in fingers and toes
- severe rash, blisters or bleeding in the lips, eyes, mouth, nose or genitals
- sudden tiredness, dizziness or sudden shortness of breath
- yellowing of the skin or the eyes

These are serious side effects. You may need medical attention. Serious side effects are rare.

##### Additional side effects

Inform the doctor if you notice any of the following side effects and are worried about them:

- nausea (feeling sick) or vomiting
- diarrhea, pain in the stomach
- dizziness, vertigo, loss of balance, may continue for months or longer after **Lariam** treatment is stopped
- headache
- itching
- insomnia (inability to sleep)
- mouth ulcers
- edema
- alopecia

These are the most frequent side effects. They are generally mild and their incidence may decrease with continued use of the medicine.

If one of the side effects worsens, or if you suffer from a side effect not mentioned in the leaflet, consult with the doctor.

#### 5) HOW SHOULD THE MEDICINE BE STORED?

- Avoid poisoning! This medicine and any other medicine may be kept in a safe place out of the reach of children and/or infants to avoid poisoning. Do not induce vomiting unless explicitly instructed to do so by the doctor.
- Do not use the medicine after the expiry date (exp. date) that appears on the package and the blister pack. The expiry date refers to the last day of that month.
- Storage conditions: Do not store above 30°C. Store the medicine in its original package (the medicine is sensitive to moisture).

#### 6) FURTHER INFORMATION

In addition to the active ingredient, the medicine also contains: Poloxamer 3800, microcrystalline cellulose, lactose monohydrate, maize starch, croscopolvidone, ammonium calcium alginate, talc and magnesium stearate.

Each **Lariam** tablet contains about 51 mg lactose monohydrate.

**What does the medicine look like and what are the contents of the package?**

**Lariam** tablets are white and cylindrical. A hexagon and the letters RO, C, HE are printed on one side of the tablets. The tablets have a scoreline in order to enable easy splitting into halves or quarters.

**Lariam** is sold in packs of 8 tablets.

License holder and address: Roche Pharmaceuticals (Israel) Ltd., P.O.B. 6391, Hod Hasharon 4524079.

Manufacturer and address: F. Hoffmann-La Roche Ltd., Basel, Switzerland.

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