Lariam[®]

Consumer Medicine Information (CMI) summary

The full CMI on the next page has more details. If you are worried about using this medicine, speak to your doctor or pharmacist.

1. Why am I using Lariam®?

Lariam® contains the active ingredient mefloquine. Lariam® is used to is used to prevent and treat malaria.

For more information, see Section 1. Why am I using Lariam®? in the full CMI.

2. What should I know before I use Lariam®?

Do not use if you have ever had an allergic reaction to mefloquine or any of the ingredients listed at the end of the CMI.

Talk to your doctor if you have any other medical conditions, take any other medicines, or are pregnant or plan to become pregnant or are breastfeeding.

For more information, see Section 2. What should I know before I use Lariam®? in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with Lariam® and affect how it works.

A list of these medicines is in Section 3. What if I am taking other medicines? in the full CMI.

4. How do I use Lariam®?

- Your doctor will tell you how many Lariam® tablets to take and how often to take them.
- For treatment of malaria, the first dose of Lariam® is 3 tablets. This is followed by a second dose of 2 tablets, 6 8 hours later. The total dose of Lariam® is usually 5 tablets.
- For prevention of malaria, the dose is 1 tablet of Lariam® once weekly, always on the same day. The first tablet should be taken one week before you arrive in the malarial area. Subsequently, take 1 tablet for each week that you remain in the malarial area and 1 tablet per week for two weeks after you have left the malarial area.

More instructions can be found in Section 4. How do I use Lariam®? in the full CMI.

5. What should I know while using Lariam®?

Things you should do	 Remind any doctor, dentist or pharmacist you visit that you are using Lariam®. Tell your doctor if you feel Lariam® is not helping your condition or if for any reason you have not taken Lariam® exactly as prescribed. Tell your doctor immediately if you become pregnant while taking Lariam®.
Things you should not do	 Do not stop using this medicine suddenly or change the dose without consulting your doctor. Do not use Lariam® to treat other complaints unless instructed by your doctor or share Lariam® with anyone else.
Driving or using machines	 Lariam® may cause dizziness, drowsiness or loss of balance in some people. These effects may occur for some time after stopping Lariam® treatment. Make sure you know how you react to Lariam® before doing anything that could be dangerous.
Drinking alcohol	Alcohol can worsen the dizziness, drowsiness or loss of balance caused by Lariam®.
Looking after your medicine	 Keep your tablets in the blister pack until it is time to take them. Keep Lariam® in a cool dry place where the temperature stays below 30°C and out of reach of children.

For more information, see Section 5. What should I know while using Lariam®? in the full CMI.

6. Are there any side effects?

The side effects of Lariam® can be similar to symptoms of Malaria and last months after you stop taking Lariam®. Lariam® can in rare cases cause serious side effects including mood related disorders or mental problems.

For more information, including what to do if you have any side effects, see Section 6. Are there any side effects? in the full CMI.

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Lariam®

Active ingredient(s): mefloquine

Consumer Medicine Information (CMI)

This leaflet provides important information about using Lariam®. You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about using Lariam®.

Where to find information in this leaflet:

- 1. Why am I using Lariam®?
- 2. What should I know before I use Lariam®?
- 3. What if I am taking other medicines?
- 4. How do I use Lariam®?
- 5. What should I know while using Lariam®?
- 6. Are there any side effects?
- 7. Product details

1. Why am I using Lariam®?

Lariam® contains the active ingredient mefloquine.

Lariam® belongs to a group of medicines called quinolones (pronounced kwin-o-lones).

Lariam® is used to prevent and treat malaria.

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

2. What should I know before I use Lariam®?

Warnings

Do not use Lariam® if:

 you are allergic to mefloquine, or related compounds quinine, quinidine or any of the ingredients listed at the end of this leaflet.

Some of the symptoms of an allergic reaction may include:

- shortness of breath
- o wheezing or difficult breathing
- swelling of the face, lips, tongue or other parts of the body
- o rash, itching or hives on the skin
- you have kidney disease
- you have severe liver disease
- the package is torn or shows signs of tampering or if the expiry date (EXP) printed on the pack has passed

Do not use Lariam® as a preventive medicine if:

- you have depression or have a history of psychiatric disorders, such as depression or anxiety.
- you have a history of seizures (epilepsy or convulsions).

Mental Problems

Some people who take Lariam® may have sudden serious mental problems. Symptoms of serious mental problems may include:

- severe anxiety
- hallucinations
- depression
- feeling restless
- unusual behaviour
- feeling confused

Check with your doctor if you:

- have any other medical conditions, especially the following:
 - psychiatric disorders particularly mood disturbances (e.g., anxiety, depression)
 - o heart conditions such as irregular heartbeat
 - o epilepsy (fits or seizures) or convulsions
 - o liver problems
 - o malaria
- have recently had a vaccination
- are planning to travel to areas where Lariam® may not be an effective treatment (i.e., areas where there is an increased risk of drug resistance such as South-East Asia)
- contact your doctor or travel health clinic before travelling for current advice on treatment and precautionary measures
- take any medicines for any other condition

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them. See additional information under Section <u>6</u>. <u>Are there any side effects</u>?

Pregnancy and breastfeeding

Check with your doctor if you are pregnant or intend to become pregnant.

If there is a need to take Lariam® during your pregnancy, your doctor will discuss with you the risks and benefits of using it.

Talk to your doctor if you are breastfeeding or intend to breastfeed.

Lariam® passes into breast milk and may affect your baby. Therefore, your doctor will discuss the risks and benefits of taking Lariam® if you are breastfeeding.

Precautions against malaria

The best protection 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 this period, wear light-coloured 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 welltucked under the mattress.
- additional protection is provided by smoke spirals, insect sprays and candles.

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 unexplained fever with or without other symptoms such as headache, aching limbs, weakness, shaking, chills, and sometimes diarrhoea, vomiting and cough. These symptoms can easily be confused with influenza.

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. The less dangerous forms of malaria, which are not lifethreatening, 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 and business travellers will normally be able to receive medical attention. However, if this is not readily available, anti-malarial drug treatment can be self-administered ('stand-by treatment').

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

There are many different types of medicines used for the treatment and prevention of malaria. Your doctor may have prescribed Lariam® for another purpose. Ask your doctor if you have any questions about why Lariam® has been prescribed for you.

Lariam® is not addictive.

3. What if I am taking other medicines?

Tell your doctor or pharmacist if you are taking any other medicines, including any medicines, vitamins or supplements that you buy without a prescription from your pharmacy, supermarket or health food shop.

Some medicines must not be taken with Lariam® or after Lariam® has been taken. It may cause serious heart problems.

Tell your doctor if you are taking or have taken recently:

- halofantrine, a medicine used to treat malaria which is available overseas in some countries.
- quinine, a medicine used to treat cramps or malaria.
- quinidine, a medicine used to treat a heart problem called atrial fibrillation.
- ketoconazole, an antifungal medicine used to treat infections.

Some medicines may interfere with Lariam® and affect how it works

These include:

- chloroquine, a medicine used to treat or prevent malaria.
- rifampicin, a medicine used to treat infections.
- medicines used to treat fits, seizures or convulsions (epilepsy) such as valproic acid, carbamazepine, phenobarbital and phenytoin.
- medicines used to treat or prevent irregular heartbeat.
- medicines used to treat high blood pressure, including groups of medicines called beta-blockers and calcium channel blockers.
- medicines used to lower blood sugar (treat diabetes).
- medicines used to prevent blood clots.
- some medicines used to treat depression and other mental disorders, including a group called tricyclic antidepressants.
- some antihistamines and medicines used to prevent or relieve the symptoms of allergy, including promethazine and trimeprazine.
- a group of medicines known as phenothiazines, used to treat mental problems, including prochlorperazine, chlorpromazine, trifluoperazine and fluphenazine.
- typhoid vaccines. You should not be vaccinated against typhoid with a 'live' vaccine while taking Lariam®. Live typhoid vaccinations should be completed at least three days before the first dose of Lariam®. Ask your doctor or pharmacist if you are not sure if your vaccine is 'live'.

These medicines may be affected by Lariam®, or may affect how well it works. You may need to take different amounts of your medicine, or you may need to take different medicines. Your doctor will advise you.

Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect Lariam[®].

4. How do I use Lariam®?

How much to take / use

- Take Lariam® exactly as your doctor has prescribed.
- Your doctor will tell you how many Lariam® tablets to take and how often to take them.
- Follow the instructions provided and use Lariam® until your doctor tells you to stop.

For treatment of Malaria

The first dose of Lariam® is 3 tablets. This is followed by a second dose of 2 tablets, 6 - 8 hours later.

• The total dose of Lariam® is usually 5 tablets.

For prevention of Malaria

- The dose is 1 tablet of Lariam® once weekly, always on the same day. Take the first tablet one week before you arrive in the malarial area.
- Take 1 tablet each week that you are in a malarial area.
- Continue to take 1 tablet per week for two weeks after you have left the malarial area.

When to take / use Lariam®

It does not matter if you take Lariam® before or after food.

How to take Lariam®

Swallow tablets whole with a full glass of water.

If you forget to use Lariam® for treatment of Malaria

Lariam® should be used regularly at the same time each day. If you forget to take the second dose of Lariam® for the treatment of malaria, take it as soon as you remember and contact your doctor.

If it is almost time for your next dose, skip the dose you missed and take your next dose when you are meant to.

Do not take a double dose to make up for the dose you missed.

If you forget to use Lariam® for prevention of Malaria

Lariam® should be used regularly at the same time each week. If you forget to take a dose, take it as soon as you remember and then go back to taking it as you would normally once a week.

If you think you may have trouble remembering your dose, ask your pharmacist for some hints.

If you use too much Lariam®

If you think that you have used too much Lariam®, you may need urgent medical attention.

You should immediately:

- phone the Poisons Information Centre (by calling 13 11 26), or
- contact your doctor, or
- go to the Emergency Department at your nearest hospital.

You should do this even if there are no signs of discomfort or poisoning.

5. What should I know while using Lariam[®]?

Things you should do

Call your doctor straight away if you:

become pregnant while taking Lariam[®].

- Women of child-bearing potential should use effective contraception while taking Lariam® and for at least three months after taking the last dose.
- Tell your doctor if, for any reason, you have not taken your medicine exactly as prescribed. Otherwise, your doctor may think that it was not effective and change your treatment unnecessarily.
- If you are taking Lariam® for the treatment of malaria, tell your doctor if you feel it is not helping your condition.
- Be sure to keep all of your appointments with your doctor so that your progress can be checked.

Remind any doctor, dentist or pharmacist you visit that you are using Lariam®.

Things you should not do

- Do not stop taking Lariam® or change the dose without first checking with your doctor.
- Do not let yourself run out of Lariam® over the weekend or on holidays.
- Do not give Lariam® to anyone else even if they have the same condition as you.
- Do not use Lariam® to treat other complaints unless your doctor says to.
- Do not take any other medicines whether they require a prescription or not without first telling your doctor or consulting a pharmacist.

Driving or using machines

Be careful before you drive or use any machines or tools until you know how Lariam® affects you.

Lariam® may cause dizziness, drowsiness or loss of balance in some people. These effects may occur for some time after stopping Lariam® treatment. Do not drive if you experience these side effects.

Drinking alcohol

Tell your doctor if you drink alcohol.

Alcohol may worsen the dizziness, drowsiness or loss of balance caused by Lariam[®].

Looking after your medicine

Keep your tablets in the blister pack until it is time to take them. If you take the tablets out of the blister pack they will not keep well.

Keep Lariam® in a cool dry place where the temperature stays below 30°C.

Follow the instructions in the carton on how to take care of your medicine properly.

Store it in a cool dry place away from moisture, heat or sunlight; for example, do not store it:

- in the bathroom or near a sink, or
- in the car or on window sills.

Keep it where young children cannot reach it.

Getting rid of any unwanted medicine

If you no longer need to use this medicine or it is out of date, take it to any pharmacy for safe disposal.

Do not use this medicine after the expiry date.

6. Are there any side effects?

All medicines can have side effects. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention.

When Lariam® is used for treatment of malaria, side effects may occur more often than when it is used for prevention of 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®.

See the information below and, if you need to, ask your doctor or pharmacist if you have any further questions about side effects.

Less serious side effects

Less serious side effects	What to do
 dizziness, vertigo (a sense of spinning) or loss of balance; these may occur after Lariam® has been stopped aching muscles, cramps, muscle tenderness or weakness, not caused by exercise headache fever, sweating or chills nausea (feeling sick) or vomiting diarrhoea, pain in the stomach fatigue, tiredness or drowsiness loss of appetite tinnitus (buzzing, hissing, whistling, ringing or other persistent noise in the ears) hair loss itching 	Speak to your doctor if you have any of these less serious side effects and they worry you.
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Serious side effects

Serious side effects	What to do
 insomnia (inability abnormal or strange) these may occur a has been stopped. change in mood, excitement, deprorestlessness, confagitation, aggress anxious or nervous ideas, hallucination thoughts or panions strange or disturb or moods; these mafter Lariam® has seizure (fit) or confiregular or racing chest pain loss of consciousments shaking or tremore difficulty breathing breath, chest tight coughing or wheeless sudden shortness tingling or number hands or feet severe skin rash, bleeding in the lipmouth, nose or geore yellowing of the seproblems with your blurred vision or entertained the severe skin or entertained the sev	straight away, or go straight to the Emergency Department at your nearest hospital if you notice any of these serious side effects. shortness of ess, ng izziness or f breath s in the sters or eyes, itals n or the eyes eyes such as

Tell your doctor or pharmacist if you notice anything else that may be making you feel unwell.

Other side effects not listed here may occur in some people.

Reporting side effects

After you have received medical advice for any side effects you experience, you can report side effects to the Therapeutic Goods Administration online at www.tga.gov.au/reporting-problems. By reporting side effects, you can help provide more information on the safety of this medicine.

Always make sure you speak to your doctor or pharmacist before you decide to stop taking any of your medicines.

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7. Product details

This medicine is only available with a doctor's prescription.

What Lariam® contains

Active ingredient (main ingredient)	Mefloquine Each Lariam® tablet contains 250 mg mefloquine as mefloquine hydrochloride.	
Other ingredients (inactive ingredients)	 microcrystalline cellulose lactose monohydrate maize starch crospovidone ammonium calcium alginate purified talc magnesium stearate poloxamer 	
Potential allergens	Lariam® does not contain sucrose, tartrazine or any other azo dyes.	

Do not take this medicine if you are allergic to any of these ingredients.

What Lariam® looks like

Lariam® is available as pack of 8 tablets (250 mg).

The tablets are white, round, and marked with 'LA', 'RI', 'AM' and 'CP' on one side. They are cross-scored so that they can be easily broken into halves or into quarters. (Aust R 43321)

Who distributes Lariam®

Pharmaco (Australia) Ltd Level 9, Tower A Zenith Towers 821 Pacific Highway Chatswood, NSE 2067 Australia

Phone: 1800 201 564

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