

LARIAM®

contains the active ingredient mefloquine

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about LARIAM tablets.

It does not contain all the available information.

It does not take the place of talking to your doctor or pharmacist.

All medicines have risks and benefits. Your doctor has weighed the risks of you taking LARIAM tablets against the benefits expected for you.

If you have any concerns about taking this medicine, ask your doctor or pharmacist.

Keep this leaflet with the medicine.

You may need to read it again.

What LARIAM is used for

LARIAM is used to prevent and treat malaria.

LARIAM contains the active ingredient mefloquine. LARIAM belongs to a group of medicines called quinolones (pronounced kwin-o-lones).

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

Where and how you can contract malaria

Malaria is an infectious disease that is widespread in tropical and subtropical areas of Africa, Latin America, Asia and countries around the Pacific. 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 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 well tucked 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 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 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.

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

Before you take LARIAM

When you must not take LARIAM

Do not take LARIAM:

1. if you have had an allergic reaction to LARIAM or related compounds quinine, quinidine
2. if you have kidney disease
3. if you have severe liver disease
4. as a preventative medicine if you have depression or have a history of psychiatric disorders, such as depression or anxiety

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

5. as a preventative medicine if you have a history of seizures (epilepsy or convulsions)
6. if you have had an allergic reaction to any of the ingredients listed at the end of this leaflet

Some of the symptoms of an allergic reaction may include;

- shortness of breath
- wheezing or difficult breathing
- swelling of the face, lips, tongue or other parts of the body
- rash, itching or hives on the skin

7. if the package is torn or shows signs of tampering
7. if the expiry date (EXP) printed on the pack has passed.

If you take this medicine after the expiry date has passed, it may not work as well.

If you are not sure if you should be taking LARIAM, talk to your doctor.

Do not give LARIAM to children under 14 years of age, unless advised to do so by the child's doctor.

Safety and effectiveness in children have not been established.

Before you start to take LARIAM

Tell your doctor if:

1. you have or have had any health problems, especially the following:

- psychiatric disorders particularly mood disturbances (e.g. anxiety, depression)
- heart conditions such as irregular heartbeat
- epilepsy (fits or seizures) or convulsions
- liver problems
- malaria

2. you have recently had a vaccination

3. you 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.

4. you are pregnant or plan 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.

5. you are breast feeding or intend to breast feed

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.

6. you are allergic to any other medicines, foods, dyes or preservatives.

If you have not told your doctor about any of the above, do so before starting LARIAM.

Taking other medicines

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

Especially 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

These medicines must not be taken with LARIAM or after LARIAM has been taken. It may cause serious heart problems.

Other medicines may interfere with LARIAM. 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.

Your doctor and pharmacist have more information on medicines to be careful with or avoid while taking LARIAM.

Ask your doctor or pharmacist if you are not sure about this list.

How to take LARIAM

Follow all directions given to you by your doctor and pharmacist carefully.

They may differ from the information contained in this leaflet.

How much LARIAM to take

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.

Treatment of malaria

The first dose of LARIAM is 3 tablets. This is followed by a second dose of 1 or 2 tablets, 6 - 8 hours later. The total dose of LARIAM is 4 to 5 tablets.

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.

How to take LARIAM

Swallow tablets whole with a full glass of water.

When to take LARIAM

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

How long to take LARIAM

Continue taking LARIAM for as long as your doctor tells you to.

The length of therapy will depend on whether LARIAM is used for the treatment or prevention of malaria.

LARIAM can be taken for up to three months for prevention of malaria.

If you stay in a malarial area for more than three months, your doctor will tell you what to do to prevent malaria.

If you forget to take LARIAM

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.

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

If you are not sure what to do, ask your doctor or pharmacist.

For the prevention of malaria, you must take 1 tablet of LARIAM once weekly, always on the same day. 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 take too much (overdose)

If you think that you or anyone else may have taken too much LARIAM, immediately telephone your doctor or Poisons Information Centre (telephone 13 11 26) for advice, or go to Accident and Emergency at your nearest hospital. Do this even if there are no signs of discomfort or poisoning.

You may need urgent medical attention.

Keep telephone numbers for these places handy.

If you are not sure what to do, contact your doctor or pharmacist.

While you are taking LARIAM

Things you must do

Tell all doctors, dentists and pharmacists who are treating you that you are taking LARIAM.

Tell your doctor immediately 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.

Things you must 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.

Things to be careful of

Be careful driving or operating machinery 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.

Make sure you know how you react to LARIAM before you drive a car, operate machinery, or do anything that could be dangerous if you are dizzy or light-headed. Do not drive if you experience these side effects. If you drink alcohol these symptoms may be worse.

Side Effects

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are taking LARIAM.

LARIAM helps most people but it may have unwanted side effects in a few people.

All medicines can have side effects. Sometimes they are serious, most of the time they are not. You may need medical treatment if you get some of the side effects.

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.

Ask your doctor or pharmacist to answer any questions you may have.

Tell your doctor if you notice any of the following and they worry you:

- 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

These are the more common or general mild side effects.

Tell your doctor immediately or go to Accident and Emergency at your nearest hospital if you experience any of the following:

- insomnia (inability to sleep) or abnormal or strange dreams; these may occur after LARIAM has been stopped

- change in mood, for example, depression, restlessness, confusion, agitation, aggression, feeling anxious or nervous, hallucinations, suicidal thoughts or panic attacks; these may occur after LARIAM has been stopped
- seizure (fit) or convulsion.
- irregular or racing heartbeat, chest pain
- loss of consciousness
- shaking or tremors
- difficulty breathing, shortness of breath, chest tightness, coughing or wheezing
- tingling or numbness in the hands or feet
- severe skin 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
- problems with your eyes such as blurred vision or eye pain.

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

This is not a complete list of all possible side effects. Others may occur in some people and there may be some side effects not yet known.

Tell your doctor if you notice anything else that is making you feel unwell, even if it is not on this list.

Ask your doctor or pharmacist if you do not understand anything in this list.

Do not be alarmed by this list of possible side effects. You may not experience any of them.

After taking LARIAM

Storage

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.

Do not store LARIAM or any other medicine, in a bathroom or near a sink.

Do not leave it in the car or on window sills.

Heat and dampness can destroy some medicines.

Keep LARIAM where children cannot reach it.

A locked cupboard at least one-and-a-half metres above the ground is a good place to store medicines.

Disposal

If your doctor tells you to stop taking LARIAM, or the tablets have passed their expiry date, ask your pharmacist what to do with any tablets that are left over.

- talc
- magnesium stearate
- poloxamer 3800.

LARIAM does not contain sucrose, tartrazine or any other azo dyes.

Manufacturer

LARIAM is distributed by:

Roche Products Pty Limited

ABN 70 000 132 865

4 - 10 Inman Road

Dee Why NSW 2099

Customer enquiries: 1800 233 950

Please check with your pharmacist for the latest Consumer Medicine Information.

Australian Registration Number:
AUST R 43321

This leaflet was prepared on 16 September 2013.

Product Description

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

What LARIAM looks like

The tablets are white, round, and marked with "RO", "C", "HE" and an imprinted hexagon on one side. They are cross-scored so that they can be easily broken into halves or into quarters.

Ingredients

Active ingredient - mefloquine

- each LARIAM tablet contains 250 mg mefloquine as mefloquine hydrochloride.

Inactive ingredients

- microcrystalline cellulose
- lactose
- maize starch
- crospovidone
- ammonium calcium alginate