

MALARONE TABLETS

Consumer Medication Information Leaflet (RiMUP)

Atovaquone/proguanil hydrochloride (250mg:100mg)

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What Malarone Tablets is used for

Malarone has two uses:

- To prevent malaria
- To treat malaria

How Malarone Tablets works

Malarone belongs to a group of medicines called antimalarials. Each tablet contains two active ingredients, atovaquone and proguanil hydrochloride. Malaria is spread by the bite of an infected mosquito, which passes the malaria parasite (*Plasmodium falciparum*) into the bloodstream. Malarone prevents malaria by killing this parasite. For people who are already infected with malaria, Malarone also kills these parasites.

Before you take Malarone Tablets

- When you must not use it

Do not take Malarone:

- If you are allergic (*hypersensitive*) to atovaquone, proguanil hydrochloride or any ingredient
- For preventing malaria, if you have severe kidney disease

Tell your doctor if any of these apply to you.

- Before you start to take it

Follow the instructions listed in the sections below before you start taking Malarone Tablets.

- Pregnancy and breast feeding

If you are pregnant, do not take Malarone unless your doctor recommends it.

Ask your doctor or pharmacist for advice before taking Malarone. Do not breast feed while taking Malarone, as the ingredients of Malarone may pass into breast milk and may harm your baby.

- Taking other medicines

Tell your doctor or pharmacist if you're taking any other medicines, or has recently taken any, including medicines bought without a prescription. Some medicines can affect the way Malarone works, or Malarone itself can strengthen or weaken the effectiveness of other medicines taken at the same time. These include:

- Metoclopramide, used to treat nausea and vomiting
- The antibiotics, tetracycline, rifampicin and rifabutin
- Efavirenz or certain highly active protease-inhibitors used to treat HIV
- Warfarin and other medicines that stop blood clotting
- Etoposide used to treat cancer

Tell your doctor or pharmacist if you are taking any of these. Your doctor may decide that Malarone isn't suitable for you, or that they need extra check ups while taking it. Remember to tell your doctor if you start taking any other medicines while taking Malarone.

How to use Malarone Tablets

Follow all directions given to you by your doctor and pharmacist carefully. They may differ from the information contained in this leaflet. If you do not understand the instructions on the label, ask your doctor or pharmacist for help.

- How much to use

To prevent malaria

The usual dose for adults is 1 tablet once a day, taken as below.

Not for children, talk to your doctor.

Not recommended for preventing malaria in children, or in adults who weigh less than 40kgs.

There may be a different type of Malarone tablet available for children in your country.

To prevent malaria in adults:

- Start taking Malarone 1 to 2 days before travelling to an area which has malaria
- Continue taking it every day during your stay
- Continue taking it for another 7 days after your return to a malaria-free area

To treat malaria

The usual dose for adults is 4 tablets once a day for 3 days. For children the dose depends on their bodyweight:

- 11-20kg – 1 tablet once a day for 3 days
- 21-30kg – 2 tablets once a day for 3 days
- 31-40kg – 3 tablets once a day for 3 days
- Over 40kg – dose as for adults

Not recommended for treating malaria in children who weigh less than 11 kgs.

For children who weigh less than 11kg talk to your doctor. There may be a different type of Malarone tablet available in your country.

- When to use it

Always give Malarone exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure. Take Malarone with food or a milky drink, where possible.

This will increase the amount of Malarone your body can absorb, and make the treatment more effective. It is best to take Malarone at the same time each day.

- How long to use it

Keep taking Malarone for 7 days after you return to a malaria-free area. Take the full course of Malarone for maximum protection. Stopping early puts you at risk of getting malaria, as it takes 7 days to ensure that any parasites that may be in your blood following a bite from an infected mosquito are killed.

Do not take Malarone for longer than 37 days. If you are expecting your child to stay in area with malaria for more than 28 days check with your

doctor before travelling. Malarone may not be suitable.

- *If you forget to use it*

It is very important that you take the full course of Malarone. If you forget to take a dose, don't worry. Just take your next dose as soon as you remember. Then continue your treatment as before. Don't take a double dose to make up for a missed dose.

- *If you take too much (overdose)*

Contact a doctor or pharmacist for advice. If possible show them the Malarone pack.

While you are using Malarone Tablets

- *Things you must do*

Use your medicine exactly as your doctor has told you.

If you have serious side effects, or if you notice any side effects not listed in this leaflet, tell your doctor or pharmacist.

Tell all the doctors, dentists and pharmacists treating you that you are using Malarone Tablets

Take Malarone Tablets only with a doctor's prescription.

- *Things you must not do*

This medicine has been prescribed for you personally. Don't pass it on to other people – It may harm them even if their symptoms seem to be the same as yours.

- *Things to be careful of*

Protecting yourself from catching malaria

People of any age can get malaria. It is a serious disease, but is preventable. As well as taking Malarone, it is very important that you also take steps to avoid being bitten by mosquitoes.

- Use insect repellent on exposed areas of the skin
- Wear light coloured clothing that covers most of the body, especially after sunset as this is the time when mosquitoes are most active

- Sleep in a screened room or under a mosquito net impregnated with insecticide
- Close windows and doors at sunset, if they are not screened
- Consider using an insecticide (mats, spray, plug-ins) to clear a room of insects or to deter mosquitoes from entering the room

If you need further advice, talk to your doctor or pharmacist.

It is still possible to get malaria after taking the necessary precautions. Some types of malaria infection take a long time to cause symptoms, so the illness may not start until several days, weeks or even months after returning from abroad.

See a doctor immediately if your child gets symptoms after returning from abroad – such as high temperature, headache, shivering and tiredness.

Driving and using machines

If you feel dizzy, do not drive. Malarone makes some people feel dizzy. If this happens to you, do not drive, use machines or take part in activities where you may put yourself or others at risk and contact your doctor immediately.

If you are sick (vomit):

For preventing malaria:

- if you are sick (*vomit*) within 1 hour of taking Malarone, take another dose straight away
- It is important to take the full course of Malarone. If you have to take extra tablets due to sickness, you may need another prescription.
- If you have been vomiting, it is especially important to use extra protection, such as repellants and bednets. Malarone may not be as effective, as the amount absorbed will be reduced.

For treating malaria:

- If you have vomiting and diarrhea tell your doctor, you will need regular blood tests. Malarone will not be as effective, as the amount absorbed will be reduced. The tests will check whether the malaria parasite is being cleared from your blood.

Side effects

Like all medicines, Malarone Tablets can cause side effects, although not everybody gets them.

Look out for the following severe reactions. They have occurred in a small number of people, but their exact frequency is unknown.

Severe allergic reactions – signs include:

- Rash and itching
- Sudden wheezing, tightness of the chest or throat, or difficulty breathing
- Swollen eyelids, face, lips, tongue or other part of the body

Contact a doctor immediately if you get any of these symptoms. Stop taking Malarone.

Severe skin reactions

- Skin rash which may blister and looks like small targets (central dark spots, surrounded by paler area with a dark ring around the edge) (*erythema multiforme*)
- Severe widespread rash with blisters and peeling skin, particularly occurring around the mouth, nose, eyes and genitals (*Stevens-Johnson syndrome*)

If you notice any of these symptoms contact a doctor urgently.

Most of the other side effects reported have been mild and have not lasted very long.

Very common side effects

These may affect more than 1 in 10 people:

- Headache
- Feeling sick and being sick (*nausea and vomiting*)
- Stomach pain
- Diarrhea

Common side effects

These may affect up to 1 in 10 people:

- Dizziness
- Sleeping problems (*insomnia*)
- Strange dreams
- Depression
- Loss of appetite
- Fever
- Rash which may be itchy
- Cough

Common side effects which may show up in blood tests are:

- Reduced numbers of red blood cells (*anaemia*) which can cause

tiredness, headaches and shortness of breath

- Reduced numbers of white blood cells (*neutropenia*) which may make you more likely to catch infections
- Low levels of sodium in the blood (*hyponatraemia*)
- An increase in liver enzymes

Uncommon side effects

These may affect up to 1 in 100 people:

- Anxiety
- An unusual awareness of abnormal beating of the heart (*palpitations*)
- Swelling and redness of the mouth
- Hair loss

Uncommon side effects that might show up in blood tests:

- An increase in amylase (*an enzyme produced in the pancreas*)

Other side effects

Other side effects have occurred in a small number of people but their exact frequency is unknown.

- Inflammation of the liver (*hepatitis*)
- Blockage of the bile ducts (*cholestatis*)
- Increased heart rate (*tachycardia*)
- Inflammation of the blood vessels (*vasculitis*) which may be visible as red or purple raised spots on the skin, but can affect other parts of the body
- Fits (seizures)
- Panic attacks, crying
- Seeing or hearing things that are not there (*hallucinations*)
- Nightmares
- Mouth ulcers
- Blisters
- Peeling skin
- Increased sensitivity of the skin to sunlight

Other side effects, which may show up in blood tests are:

- A decrease in all types of blood cells (*pancytopenia*)

If you get any side effects

If any of the side effects gets serious or troublesome, or if you notice any side effects not listed in this leaflet: Tell a doctor or pharmacist.

Visit your doctor or pharmacist immediately if you experience any side effects after using this medicine.

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by visiting the website npra.gov.my [Consumers → Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI)].

Storage and Disposal of Malarone Tablets

- Storage

Keep out of the reach and sight of children.

Do not take Malarone after the expiry date printed on the carton.

Store below 30°C.

- Disposal

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

Product Description

- What it looks like

Malarone tablets are round, pink film-coated tablets, engraved 'GX CM3' on one side. They are supplied in blister packs containing 12 tablets.

- Ingredients

- Active ingredients

- 250mg of atovaquone and 100mg of proguanil hydrochloride in each tablet.

- Inactive ingredients

- polyethylene glycol 8000, povidone K30, poloxamer 188, low substituted hydroxypropyl cellulose, pink colour concentrate OY-S-24972, magnesium stearate, macrogol 400, sodium starch glycollate, ethanol, microcrystalline cellulose.

Tell your doctor, without taking Malarone if you might be allergic to any of these ingredients.

- MAL number:

MAL20014470ACRZ

Manufacturer

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Product Registration Holder

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