

Malarone® tablets

Patient Information Leaflet

Please read this information carefully before taking your medication. If you have any questions ask your doctor or pharmacist.

What is Malarone?

The name of your medicine is Malarone.

Malarone tablets are round, pink film-coated tablets. Each tablet contains the active ingredients atovaquone 250mg and proguanil hydrochloride 100mg.

There are also some inactive ingredients in Malarone tablets. These are: poloxamer 188, microcrystalline cellulose, hydroxypropyl cellulose, povidone K30, sodium starch glycolate, magnesium stearate, methylhydroxypropyl cellulose, titanium dioxide (E171), iron oxide red (E172), macrogol 400 and polyethylene glycol 8000.

Malarone comes in blister packs of 12 tablets.

Who makes Malarone?

Glaxo Wellcome GmbH & Co., Bad Oldesloe, Germany makes Malarone and GlaxoSmithKline UK, Stockley Park West, Uxbridge, Middlesex UB11 1BT is licensed to sell it in the UK.

What is Malarone used for?

Malarone belongs to a group of medicines called antimalarials. It is used as a form of protection (prophylaxis) against malaria and to treat malaria caused by an infection of the blood with the parasite *Plasmodium falciparum*. Malarone contains two active ingredients which work by killing the malarial parasites in your body to treat or prevent the malaria infection.

What should I check before taking Malarone?

This medicine suits most people but there are a few people who should not take it. Ask yourself these questions to check whether Malarone is right for you:

- Have you ever had an allergic reaction to atovaquone, proguanil hydrochloride or to any of the other ingredients in Malarone listed above?
- Have you been told that your malaria infection is severe and is affecting your lungs, kidneys and/or brain?
- Have you had malaria before?
- Are you pregnant, trying to become pregnant, or breast-feeding?
- Are you currently suffering from diarrhoea and/or vomiting?
- Do you have kidney disease?
- Is the medicine to be taken for the treatment of malaria by a child who weighs less than 11kg?
- Is the medicine to be taken for the prevention of malaria and you or the patient weigh less than 40kg?
- Are you expecting to stay in an area where there is malaria for more than 28 days?

If the answer is "YES" to any of these questions, tell your doctor.

What if I am taking other medicines?

Always tell your doctor about any other medicines you are taking, including those you can buy yourself.

Some medicines can stop Malarone working properly, these are:

- Metoclopramide - used to treat sickness (vomiting) and feelings of sickness (nausea).
- Tetracycline, rifampicin or rifabutin - antibiotics
- Indinavir

How do I take Malarone?

It is important to take your medicine at the right times, and in the way your doctor has told you to. The label on your pack will tell you how many tablets to take and how often. If the label doesn't say, or if you are not sure, ask your doctor or pharmacist.

Malarone can be taken for two reasons:

- To prevent malaria infection (prophylaxis)
- To treat malaria infection

The following important information applies whether you are taking your Malarone tablets **for prevention or treatment of malaria**

- If possible take Malarone tablets with food or a milky drink, so that the medicine is absorbed better and works properly.
- It is also important to take your tablets at the same time each day and complete the full course.
- If you are sick (vomit) within one hour of taking your tablets, take another dose and then go on as before. If you do this you should contact your doctor for more Malarone tablets to replace those you brought up. If you have diarrhoea, continue taking these tablets as normal.
- If you feel ill again, particularly if you develop a fever at any time up to a month after finishing your tablets see your doctor immediately.
- There are no special doses for elderly patients.

To prevent malaria infection

If you are expecting to stay in an area with malaria for more than 28 days check before travelling, with a pharmacist or doctor, whether Malarone tablets are appropriate for you.

- The usual dose in adults is one tablet daily.
- Start the course of tablets 1 to 2 days before arriving in an area which has malaria
- Continue taking these tablets every day during your stay
- Continue taking these tablets for a further 7 days after your return to a malaria free area.

This may be different to how other medicines are used to prevent malaria, however, it is important to follow these instructions unless your doctor has told you otherwise.

If you weigh less than 40 kilograms (Kg), it is recommended that you do NOT take Malarone to prevent malaria infection. There is other very important information on how, in addition to taking Malarone, you can protect yourself against malaria infection at the end of this leaflet.

To treat malaria infection

The usual dose in adults is four tablets once a day for 3 days.

The dose for children depends upon their bodyweight, as follows:

- | | |
|------------|--------------------------------|
| 11-20kg: | ONE tablet daily for 3 days |
| 21-30kg: | TWO tablets daily for 3 days |
| 31-40kg: | THREE tablets daily for 3 days |
| Over 40kg: | Dose as for adults. |

If you are taking Malarone to treat an attack of malaria and you have diarrhoea or are sick (vomit), tell your doctor. Your doctor may want to check how well these tablets are working and if necessary may decide to change your treatment. A few days after finishing your treatment course you should visit your doctor to check that your malaria has been fully treated.

What to do if you take too many tablets

It is important to stick to the dose on the label of your medicine. If you take too much Malarone, or if someone else takes your medicine by mistake, tell your doctor at once.

What to do if you miss a dose

If you forget to take a dose, don't worry. Just take one as soon as you remember and then take the next dose at the right time.

Does Malarone have side effects?

Although most people find taking Malarone causes no problems, like all medicines Malarone can have side effects, however some of these can be symptoms of malaria. The following side effects have been reported in persons taking Malarone, most of these have been mild and have not lasted very long;

- Tiredness, weakness, giddiness or breathlessness, these symptoms may mean that you are suffering from a reduction in red blood cell count (anaemia)
- A reduction in white blood cells (neutropenia)
- Disturbance of the salt balance of the body (hyponatraemia)
- Feeling sick (nausea) and/or being sick (vomiting), stomach pain, diarrhoea
- Loss of appetite
- Inflammation of the mouth (stomatitis) and mouth ulcers
- Headache
- Difficulty in sleeping (insomnia)
- Cough
- Fever
- Allergic reactions, including rash, itching and swelling
- Hair loss

Temporary increases of some enzymes produced by your liver and pancreas have been reported in some patients. You may not notice any symptoms if this happens. These substances can be measured in your blood and therefore, if you have any blood tests, remind your doctor that you are taking Malarone.

Tell your pharmacist or doctor if you get these or any other side effects from your medicine which are not mentioned here.

Looking after your Malarone tablets

Keep your Malarone tablets in a safe place where children cannot see or reach them.

Do not take Malarone tablets after the expiry date shown on the label.

If your doctor stops your treatment, do not keep any leftover tablets unless your doctor tells you to. Return any unused tablets to your pharmacist for safe disposal.

REMEMBER: This medicine is for you. Never give it to any one else. It may harm them even if they have the same symptoms as you.

More about Malaria

What is Malaria?

Malaria is a serious but preventable disease spread by the bite of an infected mosquito. Anyone, of any age, can get malaria. To protect yourself against malaria, it is important to know the risks, avoid being bitten, take preventative treatment where appropriate and seek early diagnosis and treatment if necessary.

Know the risks

It is important for all people to seek advice before travelling to an area where malaria is prevalent.

Avoid being bitten

- Wear light coloured clothing that covers most of the body especially after sunset. In particular do not forget to cover your arms and legs.
- Use insect repellent on exposed areas of the skin.
- Sleep in a screened room or under a mosquito net impregnated with insecticide. If windows and doors are not screened – close them at sunset.
- Consider the use of an insecticide (mats, spray, plug-ins) to clear a room of insects before going to bed or to deter mosquitoes from entering the room.

Your pharmacist will be able to offer advice on the appropriate products to use.

Prevention (why take a prophylactic medication?)

Antimalarial prophylactic medication can protect you against contracting malaria.

It is essential to seek medical advice on which antimalarial prevention (prophylactic) medicine to take, as Malarone may not provide adequate protection in some countries. It is important to take your tablets correctly (see "How do I take Malarone?").

Prompt treatment

A few people may still get malaria despite taking the necessary precautions.

The initial signs may be mild and often appear flu-like (fever with or without weakness, shivering, pain in the joints, headaches, diarrhoea, vomiting). **Should you develop any illness within 1 year and particularly within 3 months of returning from an area where malaria is prevalent, you must contact your doctor immediately.**

Finding out more

- You may be able to find out more from public libraries.
- **If you have any other questions** about malaria or are not sure about anything, ask your doctor or pharmacist, who will be able to advise you.

You may need to read this leaflet again. Please keep it until you have finished your medicine.

This leaflet does not tell you everything about your medicine. If you have any questions or are not sure about anything, then ask your doctor or pharmacist.

The information provided applies only to Malarone tablets.

Leaflet revised August 2002.

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