

Package Leaflet: Information for the User

Malarone®

**250 mg/100 mg film-coated tablets
atovaquone/proguanil hydrochloride**

Read right through this leaflet carefully before you start taking this medicine.

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. Keep this leaflet. You may need to read it again.

If you have any questions, ask your doctor or pharmacist (chemist).

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

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1 What Malarone is and what it's for

Malarone belongs to a group of medicines called *antimalarials*. It contains two active ingredients, atovaquone and proguanil hydrochloride.

What Malarone is for

Malarone has two uses:

- to prevent malaria
- to treat malaria

Dosage instructions for each use are in Section 4, *How to take Malarone*.

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.

Protect 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 you get symptoms such as high temperature, headache, shivering and tiredness after returning home.

2 Before you take Malarone

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 either of these apply to you.

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.

Other medicines and Malarone

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

3 While you're taking Malarone

Taking Malarone with food and drink

Take Malarone with food or a milky drink, where possible. This will increase the amount of Malarone your body can absorb, and make your treatment more effective.

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.

If you are sick (vomit):

For preventing malaria:

- if you are sick (vomit) within 1 hour of taking your Malarone tablet, 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 repellents and bednets. Malarone may not be as effective, as the amount absorbed will be reduced.

For treating malaria:

- if you have vomiting and diarrhoea 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.

4 How to take Malarone

Always take 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.

It is best to take Malarone at the same time each day.

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 40 kgs.

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:

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

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

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

If you take too much Malarone

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

If you forget to take Malarone

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.

Don't stop Malarone without advice

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 to stay in an area with malaria for more than 28 days check with your doctor before travelling. Malarone may not be suitable for you.

5 Possible side effects

Like all medicines, Malarone 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
- diarrhoea.

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 your 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 may show up in your 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 (*cholestasis*)
- increase in 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 that may show up in your blood tests:

- 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.**

6 How to store Malarone

Keep Malarone out of the reach and sight of children.

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

Malarone does not require any special storage conditions.

If you have any unwanted Malarone, don't dispose of it in your waste water or household rubbish. Take it back to your pharmacist who will dispose of it in a way that won't harm the environment.

7 Further information

What Malarone contains

The active ingredients are:

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

The other ingredients are:

tablet core: poloxamer 188, microcrystalline cellulose, hydroxypropyl cellulose, povidone K30, sodium starch glycollate (Type A), magnesium stearate

tablet coating: hypromellose, titanium dioxide (E171), iron oxide red (E172), macrogol 400 and polyethylene glycol 8000.

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

What Malarone looks like and contents of the pack

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

The marketing authorisation holder is GlaxoSmithKline UK, Stockley Park West, Uxbridge, UK

The manufacturer is Glaxo Wellcome S.A., Aranda de Duero, Burgos, Spain

This medicinal product is authorised in the member states of the EEA under the following names:

All Member States MALARONE

Other formats:

To listen to or request a copy of this leaflet in Braille, large print or audio, please call, free of charge:

0800 198 5000 (UK Only)

Please be ready to give the following information:

Product name	Malarone
	250 mg/100 mg
	film-coated
	tablets

Reference number	10949/0258
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This is a service provided by the Royal National Institute of Blind People.

This leaflet was last revised in April 2011.

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