

PACKAGE LEAFLET: INFORMATION FOR THE USER

Malarone 250 mg/100 mg film-coated tablets

Atovaquone/Proguanil hydrochloride

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet:

1. What Malarone is and what it is used for
2. What you need to know before you take Malarone
3. How to take Malarone
4. Possible side effects
5. How to store Malarone
6. Contents of the pack and other information

1. What Malarone is and what it is used for

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

What Malarone is used for

Malarone has two uses:

- **to prevent malaria**
- **to treat malaria**

Dosage instructions for each use are in Section 3, *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. What you need to know before you take Malarone

Do not take Malarone:

- **if you are allergic** to atovaquone, proguanil hydrochloride or any ingredient of this medicine (listed in section 6)
 - **for preventing malaria, if you have severe kidney disease.**
- Tell your doctor if either of these apply to you.

Take special care with Malarone

Talk to your doctor or pharmacist before taking Malarone if:

- you have severe kidney disease
 - your child is being treated for Malaria and weighs less than 11 kg.
- There is another tablet strength to treat children who weigh less than 11 kg (see section 3).

- **Tell your doctor or pharmacist** if any of these applies to you.

Other medicines and Malarone

Tell your doctor or pharmacist if you are taking, have recently taken or might take **any other medicines**, 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 checkups while you're taking it.
- **Remember to tell your doctor** if you start taking any other medicines while you're taking Malarone.

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.

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.

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.

3. How to take Malarone

Always take this medicine exactly as your doctor or pharmacist 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.

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.

To prevent malaria

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

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

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 recommended 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 more Malarone than you should

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 extra tablets to make up for a missed dose. Just take your next dose at the usual time.**

Don't stop taking 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.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

4. Possible Side Effects

Like all medicines, this medicine 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*).

Rare side effects

These may affect **up to 1 in 1,000 people**:

- seeing or hearing things that are not there (*hallucinations*).

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
- nightmares
- severe mental health problem in which the person loses contact with reality and is unable to think and judge clearly.
- 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*).

Reporting of side effects

If you get any side effects talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via HPRA Pharmacovigilance, Earlsfort Terrace, IRL – Dublin 2; Tel: +353 1 6764971; Fax: +353 1 6762517. Website: www.hpra.ie, email: medsafety@hpra.ie. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Malarone

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date shown on the carton. **Malarone does not require any special storage conditions.**

Do not throw away any medicines via waste water or household waste. Ask your pharmacist how to throw away medicines you no longer use. This will help protect the environment.

6. Contents of the pack and other 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 glycolate (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.

Parallel Product Authorisation Holder: IMED Healthcare Ltd, Unit 625 Kilshane Avenue, Northwest Business Park, Ballycoolin, Dublin 15, Ireland

Manufacturer: Glaxo Wellcome S.A. Avenida de Extremadura, 3 09400 Aranda de Duero, Burgos, Spain

Repackager: Cast Healthcare Ltd, Unit B6 The Business Centre, 5-7 Tobermore Road, Draperstown, Northern Ireland, BT45 7AG

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

All Member States

MALARONE

This leaflet was last revised in November 2015

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Malarone has two uses:

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- **to treat malaria**

Dosage instructions for each use are in Section 3, *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
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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.

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Pregnancy and breast feeding

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

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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 more Malarone than you should

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 extra tablets to make up for a missed dose. Just take your next dose at the usual time.**

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4. Possible Side Effects

Like all medicines, this medicine 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*).

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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*).

Rare side effects

These may affect **up to 1 in 1,000 people**:

- seeing or hearing things that are not there (*hallucinations*).

Other side effects

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

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

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Repackager: IMED Pharma Ltd, Unit 625 Kilshane Avenue, Northwest Business Park, Ballycoolin, Dublin 15, Ireland

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All Member States

MALARONE

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