What Malarone is

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

How to store Malarone

• Do not store above 25°C.
• Keep the bottle tightly closed.
• Do not freeze.

Packaging

Pack of 28 tablets

Legal Category

P
drug

Please see Summary of Product Characteristics (SPC) for full details.

Package Leaflet: Information for the User

Malarone®

250 mg/100 mg film-coated tablets

atovaquone/proguanil hydrochloride

Process

GSK-ESP-Aranda-ESARA

10000000079025

K

1

4

6

How to take Malarone

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 these parasites.

2. Before you take Malarone

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

3. While you’re taking Malarone

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
- indinavir, used to treat HIV
- warfarin and other medicines that stop blood clotting.

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 that Malarone isn’t suitable for you, or that you need extra check ups that Malarone isn’t suitable for you, or that you need extra check ups that Malarone isn’t suitable for you, or that you need extra check ups that Malarone isn’t suitable for you, or that you need extra check ups that Malarone isn’t suitable for you, or that you need extra check ups. 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 that Malarone isn’t suitable for you, or that you need extra check ups that Malarone isn’t suitable for you, or that you need extra check ups that Malarone isn’t suitable for you, or that you need extra check ups.

Driving and using machines

If you feel dizzy do not drive.

Malaria 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.

To prevent malaria

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

For treating malaria:

• If you are sick (vomit):
  • continue taking it for another 7 days
  • take extra tablets due to sickness, you may need another prescription. If you have to vomit:
    • start taking Malarone 1 to 2 days after your return to a malaria-free area.
  • 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.

Other treatments

• 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.
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 unanswered 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: polyvinyl alcohol, microcrystalline cellulose, hydroxypropyl cellulose, potassium K30, sodium starch glycollate (Type A), magnesium stearate tablet coating: hypromellose, titanium dioxide (E171), iron oxide red (E172), magnesium 400 and polyethylene glycol 8000.

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 (cholangitis)
- 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 (sarcoidosis)
- panic attacks, crying
- seeing or hearing things that are not there (hallucinations)
- nightmares
- mouth ulcers
- rashes
- peeling skin, particularly occurring around the mouth, nose, eyes and genitals (Stevens-Johnson syndrome).

If you get any side effects
If any of the side effects get serious or troublesome, or if you notice any side effects not listed in this leaflet:

- Tell a doctor or pharmacist.