

Malarone® Paediatric tablets

62.5 mg atovaquone / 25 mg proguanil hydrochloride

Patient Information Leaflet

Read this leaflet carefully before you start to give Malarone Paediatric tablets.

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

If you have further questions, please ask your doctor or your pharmacist.

This medicine has been prescribed for you/your child and you should not pass it on to others as it may harm them.

In this leaflet:

1. What Malarone Paediatric tablets are and what they are used for
2. Before taking Malarone Paediatric tablets
3. How to take Malarone Paediatric tablets
4. Possible side effects
5. Storing Malarone Paediatric tablets

The name of your medicine is Malarone Paediatric tablets

The active ingredients in Malarone Paediatric tablets are atovaquone (62.5mg) and proguanil hydrochloride (25mg).

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

Manufacturer and Marketing Authorisation Holder

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

1. What Malarone Paediatric tablets are and what they are used for

Malarone Paediatric tablets are round, pink film-coated tablets. Each tablet contains the active ingredients atovaquone 62.5 mg and proguanil hydrochloride 25 mg.

Malarone Paediatric tablets come in blister packs of 12 tablets.

Atovaquone and proguanil hydrochloride belong to a group of medicines called antimalarials. They work by killing the very small living creatures called malaria parasites. Malaria parasites are injected into people's blood when they are bitten by the type of mosquito that can carry the parasites. These malaria parasites mainly live and multiply in the red blood cells. When atovaquone and proguanil are given at the same time, they work together so that they become more effective at killing the malaria parasites.

Atovaquone and proguanil can be used to treat the type of malaria that is caused by the parasite called *Plasmodium falciparum*. This malaria parasite is the most dangerous because it causes the most severe forms of malaria.

Atovaquone and proguanil are also taken together to help prevent infections with this parasite in people who usually live in malaria-free countries but who are travelling to parts of the world where malaria can be caught from mosquito bites.

Malarone Paediatric tablets are particularly recommended for travellers to parts of the world where some other antimalarial medicines are no longer effective at preventing malaria because the *Plasmodium falciparum* malaria parasites have become resistant to them. Your doctor or travel clinic nurse will advise you if Malarone Paediatric tablets are suitable for the parts of the world to which you/your child intend to travel.

Very probably, atovaquone and proguanil can also help to prevent the less serious forms of malaria that are caused by malaria parasites other than *Plasmodium falciparum*, although this has not been proven in clinical trials.

The amounts of the active ingredients (atovaquone and proguanil) in Malarone Paediatric tablets are suitable only for the prevention of malaria and only in children and teenagers who weigh between 11 and 40 kg.

Malarone Paediatric tablets are not suitable for children who weigh less than 11 kg because the right dose of atovaquone and proguanil to prevent malaria has not yet been worked out for these children.

Also, Malarone Paediatric tablets are not suitable for children or teenagers who weigh more than 40 kg. The daily dose for these people is one Malarone (full strength) tablet per day. These full strength tablets contain four times the amounts of the active ingredients than in Malarone Paediatric tablets (see **How to take Malarone Paediatric tablets** below).

Like all antimalarials that are used to prevent malaria in travellers, Malarone Paediatric tablets cannot completely prevent infection with malaria parasites. If you/your child develop symptoms such as high temperature, headache, shivering and tiredness while taking Malarone Paediatric tablets you should contact a doctor immediately for advice, wherever you are at the time.

Remember that some types of malaria infection take a long time to cause symptoms so that the illness may not start until several days, weeks or even months after returning from abroad. If you/your child get symptoms like these after returning home, you should see your doctor immediately. It is very important to treat malaria quickly in order to prevent complications happening.

Because malaria is caught when an infected mosquito bites, preventing mosquito bites is a very important part of protecting yourself/your child against malaria infection.

In addition to taking Malarone Paediatric tablets, the following precautions can reduce the chance of being bitten by mosquitoes:

- Wear light coloured clothing that covers most of the body, especially after sunset
- Use insect repellent on exposed areas of the skin
- Sleep in a screened room or under a mosquito net
- Use flying insect killing spray in living and sleeping areas, especially after sunset.

2. Before taking Malarone Paediatric tablets

Malarone Paediatric tablets are not suitable for everyone.

Malarone Paediatric tablets must not be taken if the answer to any of the following questions is "YES" for the person who is to take the tablets. If you are not sure, talk to your doctor before you/your child starts taking Malarone Paediatric tablets.

- Has the person who is to take Malarone Paediatric tablets ever had an allergic reaction to atovaquone, to proguanil hydrochloride or to any of the other ingredients in the tablets?
- Does the person who is to take Malarone Paediatric tablets have or ever had problems with the kidneys? People whose kidneys work very poorly must not take these tablets.

Take special care with Malarone Paediatric tablets

If the person who is to take Malarone Paediatric tablets has diarrhoea, the tablets should still be taken as usual but it is possible that the protection against malaria will be less, so it is very important to prevent mosquito bites.

If you/your child is sick within one hour after taking Malarone Paediatric tablets, another dose should be taken as soon as possible.

Taking Malarone Paediatric tablets with food or drink

Malarone Paediatric tablets should be taken with food or a milky drink whenever possible because this will increase the amount of atovaquone that reaches the blood.

See **How to take Malarone Paediatric tablets** below.

Pregnancy and breast feeding

Is there any possibility that you/your child might be pregnant or is the person who is to take Malarone Paediatric tablets breast feeding? Both these situations are very unlikely in people who weigh less than 40 kg. However, atovaquone (in Malarone Paediatric tablets) is not usually given to pregnant women or to breast feeding mothers unless the risk of catching malaria is high and the person is travelling to a part of the world where Malarone is thought to be the most appropriate medicine to prevent malaria.

Taking other medicines

Some medicines must not be taken while also taking Malarone Paediatric tablets and special care is needed with some other medicines.

You/your child must not take any other antimalarial medicines, whether prescribed or bought from a pharmacist (chemist), while taking Malarone Paediatric tablets. This is unnecessary and it could also be very dangerous.

Is the person who is to receive Malarone Paediatric tablets taking any of the following medicines? If so, your doctor may still decide to prescribe Malarone Paediatric tablets but special care may be needed.

- Medicines that contain rifampicin (often used to treat tuberculosis) or a similar medicine called rifabutin. These are antibiotics that can lower the blood levels of atovaquone so they are not usually given when taking Malarone Paediatric tablets.
- Tetracycline, another antibiotic that can lower the blood levels of atovaquone
- Metoclopramide, an anti-sickness medicine that can lower the blood levels of atovaquone
- Indinavir, a medicine used to treat HIV infection. The blood levels of indinavir are lower when it is taken with medicines that contain atovaquone.

Tell your doctor about all other medicines that the person who is to receive Malarone Paediatric tablets is taking, including those that have been bought without a prescription.

3. How to take Malarone Paediatric tablets

It is important that you/your child take Malarone Paediatric tablets exactly as your doctor has advised. If you are not sure about anything, ask your doctor or pharmacist.

In order to prevent malaria, it is important that you/your child starts to take Malarone Paediatric tablets **1 or 2 days before travelling** to a country or countries where there is a risk of catching malaria through being bitten by infected mosquitoes.

Malarone Paediatric tablets should be taken each day while in these countries and for **7 days after returning home**.

If the trip will include visits to some areas or countries where malaria is a problem and also to some where it is not a problem, it is important to continue to take Malarone Paediatric tablets until 7 days after leaving the last area or country where malaria can be caught.

Usually, Malarone Paediatric tablets should not be taken for more than 28 days. However, these tablets have been taken for 12 weeks in clinical trials. Your doctor or travel clinic nurse will advise on how long to take the tablets.

The usual daily dose of Malarone Paediatric tablets that is needed to prevent malaria depends on the weight of the person who is to receive the tablets, as shown in the table.

Weight (kg)	Number of Malarone Paediatric tablets
11-20	1 Malarone Paediatric tablet daily
21-30	2 Malarone Paediatric tablets as a single dose daily
31-40	3 Malarone Paediatric tablets as a single dose daily

People who weigh more than 40 kg can also be given atovaquone and proguanil to prevent malaria but they need one full strength Malarone tablet each day.

Each full strength Malarone tablet contains four times the amounts of the active ingredients than in each Malarone Paediatric tablet (that is 250 mg atovaquone and 100 mg proguanil hydrochloride).

If you/your child will be taking Malarone Paediatric tablets but will be travelling with other people who will need to take the full strength Malarone tablets, it is very important that the two types of tablets are kept separately in their original packages and are not mixed up.

Malarone Paediatric tablets (whether the dose is one, two or three tablets each day) should be taken once a day and at about the same time each day.

If possible, the tablets should be swallowed whole and taken with food or a milky drink because the active ingredients are absorbed better from the stomach.

If the tablets are being given to a small child who has difficulty swallowing whole tablets, they can be crushed just before being taken and mixed with food.

If you/your child is sick within one hour of taking the tablets, a repeat dose should be given.

What to do if you/your child takes too many Malarone Paediatric tablets

If you/your child have, or think you may have, taken more than the usual daily dose, you should contact your doctor or pharmacist or go to the nearest hospital emergency department for further advice.

What to do if you/your child misses a dose

If you forget to take or to give a dose, you should take or give the missed dose as soon as possible. Do not take or give a double dose to make up for a missed dose. Then go on as before.

4. Possible side effects

Like all medicines, Malarone Paediatric tablets can have side effects.

In clinical trials, stomach pains, diarrhoea, feeling sick, being sick, headache and fever were common (occurring in more than one in a hundred persons but less than one in ten) in persons taking Malarone Paediatric tablets. However, these symptoms were just as common in persons in the trials who were not given tablets that contained active ingredients, so that they may not be side effects of Malarone Paediatric tablets.

Other side effects that have been reported during the routine use of Malarone, Malarone Paediatric tablets or one of the two active ingredients (atovaquone or proguanil) taken alone include:

- Allergic reactions including rash (sometimes with spots), itching, swelling of the face or other body parts. If you/your child notice any of these symptoms, stop taking Malarone Paediatric tablets immediately and contact your doctor for advice.
- Loss of appetite, mouth ulcers and inflammation in and around the mouth
- Headache, difficulty in sleeping or dizziness
- Hair loss
- Cough
- Low numbers of red blood cells, called anaemia, that can cause tiredness
- Low numbers of white blood cells that can cause increased risk of infections
- Low numbers of all types of blood cells, with anaemia, risk of infections and symptoms such as easy bruising, nosebleeds or prolonged bleeding from cuts and wounds
- Low levels of sodium in the blood, that can cause low blood pressure
- Abnormal results of some laboratory blood tests that measure how the liver and pancreas are working and if they are inflamed.

If the person who is taking Malarone Paediatric tablets has any symptoms not mentioned here you should tell your doctor or pharmacist.

5. Storing Malarone Paediatric tablets

Keep out of the reach and sight of children.

Store below 30°C.

Do not use Malarone Paediatric tablets after the expiry date shown on the pack.

Return any unused tablets to your doctor or pharmacist for safe disposal.

Leaflet prepared: June 2002

Malarone and the GSK logo are trade marks of the GlaxoSmithKline Group of Companies

©2002 GlaxoSmithKline Group of Companies