

Package leaflet: Information for the user

Malarone Paediatric 62.5 mg/25 mg film-coated tablets atovaquone/proguanil hydrochloride

Read all of this leaflet carefully before you start taking this medicine or give it to your child 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 or your child 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 or your child 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

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1 What Malarone Paediatric is and what it is used for

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

What Malarone Paediatric is used for

Malarone Paediatric has two uses:

- **to prevent malaria** (for children weighing between 11 kg and 40 kg)
- **to treat malaria** (for children weighing between 5 kg and <11 kg).

Dosage instructions for each use are in Section 3, *How to give Malarone Paediatric*.

Although this medicine is usually used for children and teenagers, it can also be prescribed for adults weighing less than 40 kg.

Malaria is spread by the bite of an infected mosquito, which passes the malaria parasite (*Plasmodium falciparum*) into the bloodstream. Malarone Paediatric prevents malaria by killing this parasite. For people who are already infected with malaria, Malarone Paediatric also kills these parasites.

Protect your child from catching malaria.

People of any age can get malaria. It is a serious disease, but is preventable.

As well as taking Malarone Paediatric, 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 your child gets symptoms** after returning from abroad - such as high temperature, headache, shivering and tiredness.

2 What you need to know before you give Malarone Paediatric

Do not give Malarone Paediatric:

- **if your child is allergic** to atovaquone, proguanil hydrochloride or any of the ingredients of this medicine (listed in Section 6).
- **for preventing malaria, if your child has severe kidney disease.**

→ **Tell your doctor if either of these apply to your child.**

Take special care with Malarone Paediatric

Talk to your doctor or pharmacist before you give Malarone Paediatric to your child if:

- your child has severe kidney disease
- your child is being treated for Malaria and weighs less than 5 kg or is given **Malarone Paediatric** to prevent Malaria and weighs less than 11 kg.

→ **Tell your doctor or pharmacist** if any of these applies to your child.

Other medicines and Malarone Paediatric

Tell your doctor or pharmacist if your child is taking, have recently taken or might take any other medicines, including medicines bought without a prescription.

Some medicines can affect the way Malarone Paediatric works, or Malarone Paediatric 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 your child is taking any of these. Your doctor may decide that Malarone Paediatric isn't suitable for them, or that they need extra check ups while taking it.

→ **Remember to tell your doctor** if your child starts taking any other medicines while they're taking Malarone Paediatric.

Malarone Paediatric with food and drink

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

Pregnancy and breast-feeding

If you or your child is pregnant, do not take Malarone Paediatric unless your doctor recommends it.

Do not breast-feed while taking Malarone Paediatric tablets, as the ingredients may pass into breast milk and may harm your baby.

Driving and using machines

If you feel dizzy, do not drive. Malarone Paediatric 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.

Malarone Paediatric contains sodium

This medicine contains less than 1 mmol sodium (23 mg) per tablet, that is to say essentially 'sodium free'.

3 How to give Malarone Paediatric

Always give this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

Give Malarone Paediatric with food or a milky drink, where possible. The tablets should be swallowed whole. However, for children who find them difficult to swallow, they may be crushed just before being taken and mixed with food or a milky drink.

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

If your child is sick (*vomits*)

For preventing malaria:

- **if your child is sick (*vomits*) within 1 hour of taking Malarone Paediatric**, give another dose straight away
- **it is important to take the full course of Malarone Paediatric.** If your child has to take extra tablets due to sickness, they may need another prescription.
- **if your child has been vomiting**, it is especially important to use extra protection, such as repellents and bednets. Malarone Paediatric may not be as effective, as the amount absorbed will be reduced.

For treating malaria:

- **if your child has vomiting and diarrhoea** tell your doctor. Your child will need regular blood tests. Malarone Paediatric will not be as effective, as the amount absorbed will be reduced. The tests will check whether the malaria parasite is being cleared from their blood.

To prevent malaria

The recommended dose to prevent malaria depends on your child's weight.

11-20 kg - 1 tablet once a day

21-30 kg - 2 tablets once a day (as a single dose)

31-40 kg - 3 tablets once a day (as a single dose)

- Start giving Malarone Paediatric 1 to 2 days before travelling to an area which has malaria
- Continue giving it every day during the stay
- Continue giving it for another 7 days after your return to a malaria-free area.

For maximum protection your child must take the full course of treatment.

To treat malaria

The recommended dose to treat malaria depends on your child's weight.

5-8 kg - 2 tablets once a day for 3 days

9-10 kg - 3 tablets once a day for 3 days

If your child takes more Malarone Paediatric than they should have

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

If you forget to give Malarone Paediatric

It is very important that your child takes the full course of Malarone Paediatric tablets.

If you forget to give your child a dose, don't worry. Just give the next dose as soon as you remember. Then continue the 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 giving Malarone Paediatric without advice

Keep giving Malarone Paediatric for 7 days after you return to a malaria-free area. Give the full course of tablets for maximum protection. Stopping early puts your child 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 your child gets any of these symptoms. **Stop giving Malarone Paediatric.**

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 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
- itchy, bumpy rash (hives).

Uncommon side effects that might show up in 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 bile ducts (*cholestatis*)
- increased 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
- indigestion

- mouth ulcers
- blisters
- peeling skin
- increased sensitivity of the skin to sunlight.

Other side effects, which may show up in blood tests are:

- A decrease in all types of blood cells (*Pancytopenia*).

Reporting of side effects

If your child gets any side effects talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme at: www.mhra.gov.uk/yellowcard or by searching for MHRA Yellow Card in the Google Play or Apple App Store.

By reporting side effects you can help provide more information on the safety of this medicine.

5 How to store Malarone Paediatric

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

Do not use this medicine after the expiry date which is stated on the carton after EXP. The expiry date refers to the last day of that month.

Malarone Paediatric 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 Paediatric contains

The active ingredients are: 62.5 mg of atovaquone and 25 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 (see section 2).

→ **Tell your doctor, before giving Malarone Paediatric tablets** to your child, if you think your child might be allergic to any of these ingredients.

What Malarone Paediatric looks like and contents of the pack

Malarone Paediatric tablets are round, pink film-coated tablets. They are supplied in blister packs containing 12 tablets.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder: Glaxo Wellcome UK Ltd, GSK Medicines Research Centre, Gunnels Wood Road, Stevenage Hertfordshire, SG1 2NY, UK

Manufacturer:

Aspen Bad Oldesloe GmbH, Industriestrasse 32-36, 23843 Bad Oldesloe, Germany

Or

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

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 Paediatric 62.5 mg/25 mg film-coated tablets
Reference number	10949/0363

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