

**MAFAMAZ 62.5 mg/25 mg
FILM-COATED TABLETS
atovaquone/proguanil hydrochloride**

Package leaflet: Information for the user

Read all of this leaflet carefully before you start using 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 your child only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as your child's.
- If your child gets 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 Mafamaz 62.5 mg/25 mg Film-coated Tablets are and what they are used for
2. What you need to know before you use Mafamaz 62.5 mg/25 mg Film-coated Tablets
3. How to use Mafamaz 62.5 mg/25 mg Film-coated Tablets
4. Possible side effects
5. How to store Mafamaz 62.5 mg/25 mg Film-coated Tablets
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1 What Mafamaz 62.5 mg/25 mg Film-coated Tablets are and what they are used for

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

Mafamaz 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).

Although this medicine is usually used for children and teenagers, it can 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. Mafamaz prevents malaria by killing this parasite. For people who are already infected with malaria, Mafamaz 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 giving Mafamaz, 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 such as high temperature, headache, shivering and tiredness after returning home.

2 What you need to know before you use Mafamaz 62.5 mg/25 mg Film-coated Tablets

Do not use Mafamaz:

- if your child is allergic to atovaquone/proguanil or any of the other ingredients of this medicine (listed in section 6)
- for preventing malaria, if your child has severe kidney problems.

If any of the above applies to your child, talk to your doctor before your child starts taking this medicine.

Warnings and precautions

Talk to your doctor before taking Mafamaz.

If your child is sick (vomits):

For preventing malaria:

- if your child is sick (vomits) within 1 hour of taking the tablet, give another dose straight away
- it is important to take the full course of Mafamaz. 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. Mafamaz 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, they will need regular blood tests. Mafamoz 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.

Other medicines and Mafamoz

Tell your doctor or pharmacist if your child is taking/using, has recently taken/used or might take/use any other medicine.

Some medicines can affect the way Mafamoz works, or Mafamoz 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 Mafamoz is not suitable for them, or that they need extra check ups whilst taking it.

Remember to tell your doctor if your child starts taking any other medicines while they are taking Mafamoz.

Pregnancy, breast-feeding and fertility

If your child is pregnant or breast-feeding, think they may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before using this medicine.

Pregnancy

If your child is pregnant, do not give this medicine unless your doctor recommends it.

Ask your doctor or pharmacist for advice before giving this medicine.

Breast-feeding

Do not breast-feed while taking Mafamoz, as the ingredients may pass into breast milk and may harm the baby.

Driving and using machines

Mafamoz makes some people feel dizzy. If this happens to your child they should not drive, use machines or take part in activities where they put themselves or others at risk.

3 How to use Mafamoz 62.5 mg/25 mg Film-coated Tablets

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

The recommended dose is:

To prevent malaria

The usual 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 this medicine 1 – 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 usual 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

Method of administration

Give Mafamoz with food or a milky drink, where possible. This will increase the amount of Mafamoz your child's body can absorb and make the treatment more effective. 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 Mafamoz at the same time each day.

If your child is sick (vomits) within 1 hour of taking the tablet, give another dose straight away (see also section 2).

If your child takes too much Mafamoz

Talk to a doctor or go to a pharmacist for advice. Take the medicine pack with you.

If you forget to give Mafamoz

It is very important that your child takes the full course. If you forget to give a dose, give it as soon as you remember – then continue as normal. Do not give a double dose to make up for a missed dose.

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

If you stop using Mafamoz

Use for preventing malaria: Keep giving Mafamoz 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 the medicine, ask your doctor or pharmacist.

4 Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them. The following side effects may occur:

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 using Mafamoz.

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 (may affect more than 1 in 10 people):

- headache
- feeling sick and being sick (nausea and vomiting)
- stomach pains
- diarrhoea.

Common side effects (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 (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 blood tests:

- an increase in amylase (an enzyme produced in the pancreas).

Rare side effects (may affect up to 1 in 1000 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
- severe mental health problem in which the person loses contact with reality and is unable to think and judge clearly
- nightmares
- mouth ulcers
- blisters
- peeling skin
- increased sensitivity of the skin to sunlight.

Other side effects that may show up in blood tests:

- 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

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

5 How to store Mafamoz 62.5 mg/25 mg Film-coated Tablets

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 label and carton after EXP (month, year). The expiry date refers to the last day of that month.

HDPE bottles only:

Use within 90 days of first opening

Do not use if you notice any visible signs of deterioration.

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

6 Contents of the pack and other information

What Mafamoz contains:

The active substance is atovaquone and proguanil hydrochloride. Each tablet contains 62.5 mg of atovaquone and 25 mg of proguanil hydrochloride.

The other ingredients are:

Poloxamer 188, microcrystalline cellulose (E460), povidone K30 (E2101), sodium starch glycolate (Type A), magnesium stearate (E572), hypromellose (E464), low-substituted hydroxypropyl cellulose (E463), silica colloidal anhydrous (E551), titanium dioxide (E171), red iron oxide (E172), macrogol 400 and macrogol 8000.

What Mafamoz looks like and contents of the pack

Mafamoz 62.5 mg/25 mg Film-coated Tablets are pink, round, biconvex film-coated tablets debossed with "I" on one side and "11" on the other side.

Mafamoz is available in blister packs and HDPE containers.

Pack sizes:

Alu-Alu Blister: 1, 12, 21, 24, 28, 36 film-coated tablets

Alu-PVC Blister: 1, 12, 21, 24, 28, 36 film-coated tablets

HDPE containers with 33 mm PP child-resistant closure: 100 film-coated tablets.

Not all pack sizes may be marketed.

Marketing Authorisation Holder

Teva UK Limited,
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Manufacturer

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