

**MAFAMAZ 250 mg/100 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 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 Mafamaz 250 mg/100 mg Film-coated Tablets are and what they are used for
2. What you need to know before you use Mafamaz 250 mg/100 mg Film-coated Tablets
3. How to use Mafamaz 250 mg/100 mg Film-coated Tablets
4. Possible side effects
5. How to store Mafamaz 250 mg/100 mg Film-coated Tablets
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1 What Mafamaz 250 mg/100 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 in adults and children who weigh at least 40 kg
- to treat malaria in adults and children who weigh at least 11 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 yourself from catching malaria

People of any age can get malaria. It is a serious disease, but is preventable. As well as taking 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 you get symptoms such as high temperature, headache, shivering and tiredness after returning home.

2 What you need to know before you use Mafamaz 250 mg/100 mg Film-coated Tablets

Do not use Mafamaz:

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

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

Warnings and precautions

Talk to your doctor before taking Mafamaz.

If you are sick (vomit):

For preventing malaria:

- if you are sick (vomit) within 1 hour of taking your tablet, take another dose straight away
- it is important to take the full course of Mafamaz. 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. Mafamaz 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. 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 your blood.

Other medicines and atovaquone/proguanil

Tell your doctor or pharmacist if you are taking/using, have 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 you are taking any of these. Your doctor may decide that Mafamoz is not suitable for you, or that you need extra check ups while you're using it.

Remember to tell your doctor before you start taking any other medicines while you are taking Mafamoz.

If any of the above apply to you (or you are not sure), talk to your doctor or pharmacist before using Mafamoz.

Pregnancy, breast-feeding and fertility

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

Pregnancy

If you are pregnant, do not use this medicine unless your doctor recommends it.

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

Breast-feeding

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

Driving and using machines

If you feel dizzy, do not drive. This medicine 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 use Mafamoz 250 mg/100 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 in adults and children weighing at least 40 kg.**

The usual 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 kg. There may be a different type of atovaquone/proguanil tablet available for children weighing less than 40 kg.

To prevent malaria:

- start taking Mafamoz 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 in adults and children who weigh at least 11 kg

The usual 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 kg. For children who weigh less than 11 kg talk to your doctor. There may be a different type of atovaquone/proguanil tablet available.

Method of administration

Take with food or a milky drink, where possible. It is best to take Mafamoz at the same time each day. This will increase the amount of Mafamoz your body can absorb, and make your treatment more effective.

If you are sick (vomit) within 1 hour of taking your tablet, take another dose straight away. (see also section 2).

If you use more Mafamoz than you should

If you take more than you should, talk to a doctor or go to a pharmacist for advice. Take the medicine pack with you.

If you forget to use Mafamoz

It is very important that you take the full course. If you forget to take a dose, take it as soon as you remember – then continue as normal. Do not take 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

Keep taking Mafamoz for 7 days after you return to a malaria-free area. Take the full course of Mafamoz 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. Do not stop taking Mafamoz just because you feel better.

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 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 pain
- 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 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 (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 (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 you get 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 250 mg/100 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 250 mg of atovaquone and 100 mg 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 250 mg/100 mg Film-coated Tablets are pink, round, biconvex film-coated tablets debossed with "H" on one side and "175" 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 38 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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