

PATIENT INFORMATION LEAFLET: INFORMATION FOR THE USER

Maloff Protect 250 mg/100 mg tablets atovaquone/proguanil hydrochloride

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.

Always take this medicine exactly as described in this leaflet or as your doctor or pharmacist has told you.

- Keep this leaflet. You may need to read it again.
- Ask your pharmacist or doctor if you need more information or advice.
- If you have any further questions, ask your doctor or pharmacist.
- 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.

In this leaflet:

1. What Maloff Protect is and what it is used for
2. What you need to know before you take Maloff Protect
3. How to take Maloff Protect
4. Possible side effects
5. How to store Maloff Protect
6. Contents of the pack and other information

1. WHAT MALOFF PROTECT IS AND WHAT IT IS USED FOR

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

Maloff Protect is used to prevent malaria. It is available from the pharmacy for adults. It is not suitable for use in children or adolescents unless it has been prescribed for them by a doctor. If you are under 18 and you are visiting an area where there is malaria, talk to your doctor, nurse or pharmacist for advice.

Malaria is spread by the bite of an infected mosquito, which passes the malaria parasite (*Plasmodium falciparum*) into the bloodstream. Maloff Protect prevents malaria by killing this parasite.

IMPORTANT: You must get advice from a healthcare professional about which antimalarial medicine or medicines to take. You must ask your doctor, nurse or pharmacist if Maloff Protect is suitable for the part of the world that you are visiting.

Getting advice for malaria is only one of the aspects to protect your health before your travel. Remember to seek a full travel consultation. If your travel plans change, you must seek updated travel advice.

Protect yourself from malaria

People of any age can get malaria. It is a serious disease, but it is preventable. As well as taking Maloff Protect, it is very important that you also take steps to avoid being bitten by mosquitoes. The bite avoidance measures listed below should be used in combination for maximum effectiveness.

- **Use insect repellent on exposed areas of the skin.**
 - **Wear clothing that covers most of the body,** especially after sunset as this is the time when
-

mosquitoes are most active.

- **Sleep in a room with screened windows and doors** or under a mosquito net (it is preferable to sleep under a mosquito net treated with insecticide if possible).
- **Close windows and doors at sunset**, if they are not screened.
- **Sleep in a room with air-conditioning or a fan**, as mosquitoes are less active in cooler temperatures.
- **Consider using an insecticide** (mats, spray, plug-ins) to clear a room of insects or to stop 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 these symptoms, particularly within three months but even up to one year after returning home:

- a high temperature (fever)
- headache
- tiredness
- sweats and chills
- vomiting

Tell your doctor that you have visited a malaria area.

2. WHAT YOU NEED TO KNOW BEFORE YOU TAKE MALOFF PROTECT

Do not take Maloff Protect if you:

- are allergic to atovaquone and/or proguanil hydrochloride or any of the ingredients of this medicine (listed in section 6)
- have kidney disease
- have liver disease

Do not take Maloff Protect unless it has been prescribed for you by a doctor or other qualified prescriber if you:

- are breastfeeding, pregnant or think you may be pregnant (see section 'Pregnancy and Breastfeeding')
- are under 18 years old or weigh less than 40 kg
- have ever had **epilepsy**, convulsions or fits
- suffer from **depression**
- have tuberculosis

Do not take Maloff Protect if you are already taking any of the following medicines:

- etoposide, used to treat cancer
 - metoclopramide, used to treat nausea and vomiting
 - the antibiotics tetracycline, rifampicin or rifabutin
 - indinavir, efavirenz, zidovudine or certain medicines called protease inhibitors, used to treat human immunodeficiency virus (HIV)
-

- warfarin, other coumarin based anticoagulants, or new oral anticoagulants (NOACs) such as dabigatran etexilate, rivaroxaban, and apixaban

Talk to your doctor or pharmacist for advice.

Warnings and precautions:

- If you are sick (*vomit*) **within one hour** of taking your Maloff Protect tablet, take another dose straight away. If you don't start vomiting until **more than one hour** after taking Maloff Protect, do not take another Maloff Protect tablet until your next dose is due, as it is likely that Maloff Protect will already be in your system
- It is very important to **take the full course** of Maloff Protect. If you have to take extra tablets due to sickness, you may need to get some more
- If you have been vomiting or have diarrhoea, it is especially important to use extra bite prevention, such as repellents and bed nets. The Maloff Protect you have taken may not be as effective because you may absorb less than you need

Tell your doctor or pharmacist if you have taken any medicines to prevent or treat malaria before and they have not worked or if you have had an allergic reaction to them. Maloff Protect may not be suitable for you.

Other medicines and Maloff Protect

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines. This includes medicines that you buy without a prescription.

Do not take Maloff Protect if you are taking any of the medicines listed in the above section "Do not take Maloff Protect".

REMEMBER to tell your doctor or pharmacist if you start taking any other medicines while you're taking Maloff Protect.

Maloff Protect with food and drink

Take Maloff Protect with food or a milky drink, where possible. This will increase the amount of Maloff Protect your body can absorb, and make your treatment more effective.

It is best if you swallow the tablets whole and do not crush them.

Pregnancy and breastfeeding

If you are pregnant, think you may be pregnant or intend to get pregnant, or you are breastfeeding, do not take Maloff Protect unless your doctor tells you to.

Pregnant women have an increased risk of developing severe malaria and a higher risk of fatality compared to non-pregnant women.

Seek advice from your doctor or pharmacist if you are pregnant or breastfeeding and need to take an antimalarial.

Driving and using machines

Maloff Protect makes some people feel dizzy. If you feel dizzy, do not drive, use machines or take part in activities where you may put yourself or others at risk.

3. HOW TO TAKE MALOFF PROTECT

Always take this medicine exactly as described in this leaflet or as your doctor, nurse or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

Take Maloff Protect with food or a milky drink, where possible as this helps your body absorb the active ingredients.

It is best to take Maloff Protect at the **same time each day**.

Adults: Take one tablet once a day, as described below.

- Start taking Maloff Protect one to two days before travelling to an area which has malaria.
- Continue taking it every day during your stay.
- Take Maloff Protect for another seven days after your return to a malaria-free area.
- Take the full course of Maloff Protect for maximum protection. Stopping early puts you at risk of getting malaria, as it takes seven days to ensure that any parasites that may be in your blood after a bite from an infected mosquito are killed.

Maloff Protect is only available without a prescription for adults. It is not suitable for use in children or adolescents unless it has been prescribed for them by a doctor. If you are under 18 and you are visiting an area where there is malaria, talk to your doctor, nurse or pharmacist for advice.

If you take more Maloff Protect than you should

Contact a doctor or pharmacist for advice. If possible, show them the Maloff Protect pack.

If you forget to take Maloff Protect

It is important that you take the full course of Maloff Protect. If you forget to take a dose, take your next dose as soon as you remember. Then continue your treatment as before.

Do not take a double dose (two doses at the same time) to make up for a missed dose.

Only take an additional dose if you are sick (vomit) within one hour of taking Maloff Protect. See “Warnings and precautions” overleaf.

Don’t stop taking Maloff Protect unless your doctor or pharmacist tells you to. The only exception is if you experience one of the serious side effects listed in section 4 below.

Talk to your doctor or pharmacist if you need any advice.

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

4. POSSIBLE SIDE EFFECTS

Like all medicines, Maloff Protect can cause side effects, although not everybody gets them.

IMPORTANT: If any side effect causes you to stop taking Maloff Protect, or if you vomit or have diarrhoea whilst taking Maloff Protect, you should continue to protect yourself against malaria as much as possible. Information on how to protect yourself from malaria is provided in section one of this leaflet. The bite avoidance measures listed in section one should be used in combination for maximum effectiveness.

Look out for the following severe reactions. They have occurred in a small number of people, but their exact frequency is unknown.

Stop taking Maloff Protect and contact a doctor immediately if you notice any of the following symptoms:

- **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

- **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)

Most of the following side effects reported have been mild and have not lasted very long.

Very common: may affect more than 1 in 10 people

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

Common: may affect up to 1 in 10 people

- dizziness
- sleeping problems (insomnia)
- strange dreams
- depression
- loss of appetite
- fever
- rash
- cough
- allergic reactions
- itching (pruritus)

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: may affect up to 1 to 100 people

- anxiety
 - an unusual awareness of abnormal beating of the heart (palpitations)
 - swelling and redness of the mouth
 - red swollen patches on the skin (hives)
 - hair loss
-

Uncommon side effects that may show up in your blood tests:

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

Rare: 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.

- pancytopenia (a decrease in all types of blood cells)
- 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
- nightmares
- severe mental health problem in which the person loses contact with reality and is unable to think and judge clearly
- mouth ulcers
- blisters
- peeling skin
- increased sensitivity of the skin to sunlight
- effects on your stomach (gastric intolerance)

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 Website: 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 MALOFF PROTECT

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 and the blister after EXP. The expiry date refers to the last day of that month.

This medicine does not require any special storage conditions.

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 Maloff Protect contains**

The active substances are atovaquone and proguanil hydrochloride. Each tablet contains 250 mg atovaquone and 100 mg proguanil hydrochloride.

The other ingredients are:

Core

Poloxamer 188, Microcrystalline Cellulose, Low-substituted Hydroxypropyl Cellulose, Povidone K30, Sodium Starch Glycolate Type A, Silica Colloidal anhydrous, Magnesium Stearate

Coating

Hypromellose, Titanium Dioxide (E171), Iron Oxide Red (E172), Macrogol 400, Macrogol 8000

What Maloff Protect looks like and contents of the pack

Maloff Protect tablets are pinkish brown to brown coloured, circular, biconvex bevelled edge film-coated tablets with '404' debossed on one side and 'G' debossed on the other side.

Maloff Protect tablets are supplied in PVC/PVDC (clear) and hard tempered PVC/PVDC-Aluminium foil blisters containing 12 tablets.

Pack size: 24 or 36 tablets

Marketing Authorisation Holder

Glenmark Pharmaceuticals Europe Limited
Laxmi House, 2 B Draycott Avenue,
Kenton, Middlesex, HA3 0BU,
United Kingdom

Manufacturer

Glenmark Pharmaceuticals Europe Limited.
Building 2, Croxley Green Business Park, Croxley Green,
Hertfordshire, WD18 8YA, United Kingdom

Glenmark Pharmaceuticals s.r.o.
Hvězdova 1716/2b, 140 78 Prague 4,
Czech Republic

Tillomed Laboratories Limited
3 Howard Road, Eaton Socon,
St. Neots, Cambridgeshire, PE19 8ET,
United Kingdom

This leaflet was last revised in May-2017
