

PATIENT INFORMATION LEAFLET

Read all of this leaflet carefully before you start taking this medicine

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

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

This medicine has been prescribed for you personally, and you should not pass it on to others. It may harm them, even if their symptoms are the same as yours.

SCHEDULING STATUS:

S4

PROPRIETARY NAME AND DOSAGE FORM:

MALANIL[®] Tablets.

COMPOSITION OF THE MEDICINE, THAT IS, WHAT THIS MEDICINE CONTAINS:

Each MALANIL tablet contains the active ingredients atovaquone 250 mg and proguanil hydrochloride 100 mg.

The other (inactive) ingredients are: poloxamer 188, microcrystalline cellulose, low-substituted hydroxypropyl cellulose, povidone K30, sodium starch glycollate, and magnesium stearate in the core of the tablet. The tablet coating contains: hypromellose, titanium dioxide, iron oxide red E72, macrogol 400, polyethylene glycol 8 000.

APPROVED INDICATION AND USE, THAT IS, WHAT THIS MEDICINE IS USED FOR:

MALANIL belongs to a group of medicines called antimalarials. MALANIL is used to prevent malaria caused by *Plasmodium falciparum*. MALANIL contains two active ingredients which kill the malaria parasites in your body to prevent malaria.

INSTRUCTIONS BEFORE TAKING THE MEDICINE:

If you answer “yes” to any of the following questions, tell your doctor about this before taking your medicine.

Have you been told you are allergic to atovaquone, proguanil hydrochloride or any of the other ingredients in MALANIL tablets?

Are you taking any medicines containing rifampicin, rifabutin, tetracycline or metoclopramide?

Are you taking medicine containing indinavir?

Are you taking warfarin or other medicines that prevent your blood from clotting (anticoagulants)?

Do you have problems with your kidneys?

Have you had a history of epilepsy?

Are you pregnant or likely to become pregnant soon?

Are you breastfeeding?

Always tell your health care professional if you are taking any other medicine.

If you are pregnant or breastfeeding your baby please consult your doctor, pharmacist or other health care professional for advice before taking this medicine.

INSTRUCTIONS ON HOW TO TAKE THE MEDICINE:

Do not share medicines prescribed for you with any other person.

Take MALANIL as your doctor has advised you. The usual dose of MALANIL is given below. If you are not sure, ask your doctor or pharmacist.

MALANIL should be swallowed whole with a drink. Take the tablets with food or a milky drink, as the active ingredients are absorbed better from the stomach.

For prevention of malaria MALANIL should be taken at the same time each day.

In the event of vomiting within one hour of taking a dose, a repeat dose should be taken.

In the event of diarrhoea, normal dosing should be continued and, to prevent malaria, personal protection should be used (repellents, bednets).

Your doctor may decide to give you other medicines as well as MALANIL. Please read any instruction leaflet carefully.

Prevention of malaria:

In order to prevent malaria, it is important that you take your MALANIL every day. Start taking it 1 or 2 days before travelling to a country (or countries) where malaria is transmitted, continue daily dosing while you are there and for 7 days after returning.

Adults:

One MALANIL tablet daily.

What to do if you take too much:

It is important to take only the dose of MALANIL prescribed by your doctor. In the event of overdosage, please consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison control centre.

What to do if you miss a dose:

If you forget to take a dose, take another as soon as possible. Then go on as before.

SIDE EFFECTS:

MALANIL can cause side effects, although not everyone gets them. The following side effects have been reported in people taking MALANIL or the active ingredients (atovaquone or proguanil). Most of these have been mild and have not lasted very long.

Very common side effects:

These may affect more than 1 in 10 people taking MALANIL:

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

Common side effects:

These may affect more than 1 in 100 people taking MALANIL:

- rash
- loss of appetite
- difficulty in sleeping (insomnia)
- dizziness
- fever
- cough

Other 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)
- low levels of sodium in the blood (hyponatraemia)
- an increase in liver enzymes

Uncommon side effects:

These may affect more than 1 in 1 000 people taking MALANIL:

- itching and swelling of the skin caused by an allergic reaction (urticaria)
- swelling and redness of the mouth
- hair loss

An increase in amylase (an enzyme produced in the pancreas) may show up in blood tests.

Other possible side effects:

- sudden wheezing, tightness of the chest or throat, or difficulty breathing
- swollen eyelids, face, lips tongue or other part of the body
- 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])
- **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**

- convulsions
- psychiatric disorders
- inflammation of blood vessels (vasculitis) which may be visible as red or purple raised spots on the skin, but can affect other parts of the body
- inflammation of the liver (hepatitis), yellow discolouration of the skin or eyes (jaundice)
- mouth ulcers

Reduced numbers of platelets (cells necessary for blood clotting) may show up in blood tests in people with severe kidney problems.

Not all side effects reported for MALANIL are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking this medicine, please consult your doctor, pharmacist or other health care professional for advice.

STORAGE AND DISPOSAL INFORMATION:

Store below 30 °C.

Store all medicines out of reach of children.

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

PRESENTATION:

MALANIL tablets are packed into PVC/aluminium foil blisters containing 12 tablets.

IDENTIFICATION:

MALANIL Tablets: Round, biconvex, pink film-coated tablet with a yellow core. Branded 'GX CM3'.

REGISTRATION NUMBER:

37/20.2.6/0075

**NAME AND BUSINESS ADDRESS OF THE HOLDER OF THE CERTIFICATE OF
REGISTRATION:**

LITHA PHARMA (PTY) LTD

106 16th Road

Midrand

1685

South Africa

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