# PATIENT INFORMATION LEAFLET

**SCHEDULING STATUS**

S2

**PROPRIETARY NAME, STRENGTH AND DOSAGE FORM**

**MALATEQ FILM COATED TABLETS**

Read all of this leaflet carefully before you start taking **MALATEQ** film coated tablets:

**MALATEQ** is available without a doctor's prescription. Nevertheless, you still need to use **MALATEQ** carefully to get the best results from it.

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor or your pharmacist.
- **MALATEQ** has been prescribed for you personally and you should not share your medicine with other people. It may harm them, even if their symptoms are the same as yours.

## 1. WHAT MALATEQ FILM COATED TABLETS CONTAIN:

The active substances in each **MALATEQ** film coated tablet are 250 mg atovaquone and 100 mg proguanil hydrochloride.

The other (inactive) ingredients are colloidal silicon dioxide, hydroxypropyl cellulose, magnesium stearate, microcrystalline cellulose, Opadry brown (ferric oxide, hydroxypropyl methylcellulose, polyethylene glycol, titanium dioxide), poloxamer 188, povidone and sodium starch glycolate.

## 2. WHAT MALATEQ FILM COATED TABLETS ARE USED FOR:

**MALATEQ** is indicated for the prevention of *Plasmodium falciparum* malaria. It belongs to a group of medicines called antimalarial.

**MALATEQ** is used to reduce the risk of contracting malaria caused by *Plasmodium falciparum,* a parasite. **MALATEQ** contains two active ingredients which kill the malaria parasites in your body to reduce the risk of contracting malaria.

## 3. BEFORE YOU TAKE MALATEQ FILM COATED TABLETS:

Do not take **MALATEQ** film coated tablets:

- If you are allergic to atovaquone, proguanil hydrochloride or any of the other ingredients of **MALATEQ.**
- If you have severe kidney impairment.

**Tell your doctor, pharmacist or health care provider before taking MALATEQ if:**

- You weigh less than 40 kilograms;
- You have diarrhoea or are vomiting;
- You are taking any medicines containing rifampicin, rifabutin, tetracycline or metoclopramide;
- You are taking medicine containing indinavir;
- You have problems with your kidney;
- You are pregnant or likely to become pregnant soon; and
- You are breastfeeding.

**Taking MALATEQ film coated tablets with food and drink:**

**MALATEQ** film coated tablets should be taken with food or milk.

**Pregnancy and Breastfeeding:**

Before taking **MALATEQ**, tell your doctor if you are breastfeeding, pregnant or likely to become pregnant soon.

If you are pregnant or breastfeeding your baby while taking **MALATEQ**, please consult your doctor, pharmacist or other health care provider for advice.

Safety during pregnancy and breastfeeding has not been established.

Women breastfeeding their infants should not receive **MALATEQ.**

**Driving and using machinery:**

No studies have been done to investigate the effect of **MALATEQ** on driving performance or the ability to operate machinery.

**Taking other medicines with MALATEQ film coated tablets:**

If you are using other medicines on a regular basis, including complementary or traditional medicines, the use of **MALATEQ** with these medicines may cause undesirable interactions. Please consult your doctor, pharmacist or other health care provider for advice.

Make sure your doctor knows what other medicines you are taking, including those that you have bought yourself.

Before taking **MALATEQ**, tell your doctor if:

- You are taking any medicines containing rifampicin, rifabutin, tetracycline, or metoclopramide; or
- You are taking medicines containing indinavir.

## 4. HOW TO TAKE MALATEQ FILM COATED TABLETS:

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

Always take **MALATEQ** exactly as your doctor has instructed you. You should check with your doctor or pharmacist if you are unsure.

**Prevention of malaria:**

The usual dose is:

Adults: One **MALATEQ** film coated tablet daily.

In order to prevent malaria, it is important that you take your **MALATEQ** film coated tablet every day. Start taking 1 or 2 days before travelling to an area, or a country (or countries) where malaria is transmitted. Continue daily dosing while you are there, and for 7 days after

returning. **MALATEQ** film coated tablets should be swallowed whole with a drink. Take the tablets with food or milk, as the active ingredients are then absorbed better from the stomach.

For prevention of malaria, **MALATEQ** 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 personal protection should be used (e.g. repellents, bed nets). Your doctor may decide to give you other medicines as well. Please read any instruction leaflet carefully.

Your doctor will tell you how long your treatment with **MALATEQ** will last.
Do not stop treatment because you may increase the risk of contracting malaria. If you have the impression that the effect of **MALATEQ** is too strong or too weak, tell your doctor or pharmacist.

**If you take more MALATEQ film coated tablets than you should:**
It is important to take only the dose of **MALATEQ** prescribed by your doctor.

In the event of overdosage, consult your doctor or pharmacist. If neither is available, seek help at the nearest hospital or poison control centre.

**If you forget to take MALATEQ film coated tablets:**
If you forget to take a dose, take another as soon as possible. Then go on as before. Do not take a double dose to make up for forgotten individual doses.

## 5. POSSIBLE SIDE EFFECTS

**MALATEQ** can have side effects.

Not all side effects reported for **MALATEQ** are included in this leaflet.
Should your general health worsen while taking **MALATEQ**, please consult your doctor, pharmacist or other health care provider for advice.

If any of the following happen, stop taking **MALATEQ** and tell your doctor immediately or Go to the casualty department at your nearest hospital:

- Swelling of the hands, feet, ankles, face, lips, mouth or throat which may cause difficulty in swallowing or breathing;
- Rash or itching.

These are all very serious side effects. If you have them, you may have had a serious allergic reaction to **MALATEQ**. You may need urgent medical attention or hospitalisation. All of these very serious side effects occur less frequently.

Tell your doctor immediately or go to the casualty department at your nearest hospital if you notice any of the following:

- Fever

This is a serious side effect. You may need urgent medical attention.
Serious side effects usually occur less frequently.

Tell your doctor as soon as possible, if you notice any of the following:

- Loss of appetite, feeling sick (nausea) and/or being sick (vomiting), stomach pain, diarrhoea.
- Mouth inflammation (swelling, redness, pain) and mouth ulcers.
- Allergic reactions including rash, itching and swelling.
- Headache, difficulty in sleeping, raised body temperature, hair loss, coughing.

**MALATEQ** may cause changes to the body's normal blood levels of certain cells or chemicals or lead to other blood abnormalities. If you are having a blood test for any reason, tell the person who is taking your blood sample that you are receiving **MALATEQ,** as it may affect your result. While taking **MALATEQ**, if you feel unwell or have any unusual symptoms, even those that are not mentioned in this leaflet, seek the advice of your doctor or pharmacist.

## 6. STORING AND DISPOSING OF MALATEQ TABLETS:

- Keep the medicine in its original package.
- Store at or below 25°C.
- Check the use before date shown on the carton at the time of receipt. Do not use it if out of date.
- Keep all medicines out of the reach and sight of children. It may harm them.
- Return all unused medicines to your pharmacist.
- Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).
- Do not share medicines prescribed to you with others.

## 7. PRESENTATION OF MALATEQ FILM CAOTED TABLETS:

**MALATEQ** film coated tablets are packed in white HDPE containers with white caps containing 100 tablets.

**MALATEQ** film coated tablets are packed in PVC/PVDC (clear) paper backed with push through aluminium foil blister containing 12 tablets.

## 8. IDENTIFICATION OF MALATEQ FILM COATED TABLETS:

**MALATEQ** film coated tablets: 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.

## 9. REGISTRATION NUMBER

47/20.2.6/1015

## 10. NAME, BUSINESS ADDRESS AND TELEPHONE NUMBER OF THE HOLDER OF THE CERTIFICATE OF REGISTRATION

Forrester Pharma (Pty) Ltd.

Forrester Pharma (Pty) Ltd.

2 Waterford Mews

Waterford Place

Century City

7441

Cape Town

South Africa

**11. DATE OF PUBLICATION**

December 2017

Namibia: Reg No.: 16/20.2.6/0058 NS1