

# MALARONE<sup>®</sup> Tablets (250/100)

# MALARONE<sup>®</sup> Junior Tablets

# (62.5/25)

*MALARONE (Atovaquone and Proguanil Hydrochloride)*

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## Consumer Medicine Information

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### What is in this leaflet?

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Unless explained differently, the information for "MALARONE" in this leaflet applies to both MALARONE Tablets (250/100) and MALARONE Junior Tablets (62.5/25) (refer to the "Product description" section near the end of the leaflet for a description of these two products).

Please read this leaflet carefully before you take MALARONE.

This leaflet answers some common questions about MALARONE. It does not contain all of the available information.

It does not take the place of talking to your doctor or pharmacist.

All medicines have risks and benefits. Your doctor has weighed the risks of you taking MALARONE against the benefits this medicine is expected to have for you.

**If you have any concerns about taking this medicine, ask your doctor or pharmacist.**

### Keep this leaflet with the medicine.

You may need to read it again.

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### What MALARONE is used for

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MALARONE Tablets and MALARONE Junior tablets contain the active ingredients atovaquone and proguanil hydrochloride.

This medicine belongs to a group of drugs called antimalarials.

It is used in the prevention and treatment of malaria caused by a pathogen called *Plasmodium falciparum*.

Malaria in humans is caused by four species of *Plasmodium* parasites. *Plasmodium falciparum* is the most common species in tropical areas and is transmitted primarily during the rainy season.

**Malaria** is a debilitating infectious disease characterised by chills, shaking, and periodic bouts of intense fever. Malaria is transmitted

from person to person by the bite of female mosquitos.

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### Before you take MALARONE

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#### *When you must not take MALARONE*

- Do not take MALARONE if you have ever had an allergic reaction to atovaquone or proguanil or any of the ingredients listed at the end of this leaflet.
- Do not take MALARONE if you have severe kidney problems.
- Do not take MALARONE if you are pregnant, trying to become pregnant or breastfeeding, unless your doctor says you should.

Your doctor will discuss the risks and benefits of using MALARONE if you are pregnant or breastfeeding.

- Do not take MALARONE after the expiry date (EXP) printed on the pack.

If you use the tablets after the expiry date has passed, they may not work as well.

- Do not take MALARONE if the packaging is torn or shows signs of tampering.

**If you're not sure whether you should be taking MALARONE, talk to your doctor.**

### **What you must do**

**You must tell your doctor if:**

- you are allergic to foods, dyes, preservatives or any other medicines.
- you have kidney problems
- you have been treated for malaria caused by *Plasmodium falciparum* in the past and it has occurred again
- you have diarrhoea (loose bowel motions). This may interfere with the absorption of MALARONE.
- you are an adult who weighs less than 40kg
- you are taking any medicines containing the following :
  - tetracyclines (a type of antibiotic)
  - metoclopramide (a drug used for treatment of nausea)
  - rifampicin (a drug used to treat tuberculosis)

- rifabutin (a drug used to treat bacterial infections)
- indinavir, a medicine used in the treatment of HIV infection.
- warfarin or other medicines that prevent your blood from clotting (anticoagulants).
- you are taking any other medicines, including those you buy from a supermarket, pharmacy or health food shop.
- you are breastfeeding, pregnant or trying to become pregnant.

Some medicines may affect the way others work. Your doctor or pharmacist will be able to tell you what to do when using MALARONE while taking other medicines.

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### **How to take MALARONE**

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Take your medicine as your doctor has told you.

The label on the pack will tell you how many tablets to take and how often you should take them. If you do not understand what you should do, ask your doctor or pharmacist.

MALARONE tablets should be taken with food or a milky drink at the same time each day.

For children who find the tablet(s) difficult to

swallow, the tablet(s) may be crushed and mixed with food or a milky drink just before being taken.

If you vomit within 1 hour of taking MALARONE, take another dose as soon as you can. In the event of diarrhoea, normal dosing should be continued. In addition, personal protection from mosquitoes should be used (repellants, bednets).

### **How much to take**

Take MALARONE as directed by your doctor or pharmacist.

### **Prevention of Malaria**

**Adults:** One MALARONE Tablet (250/100) daily.

**Children (11-40kg):** Depending on the child's weight, one, two or three MALARONE Junior Tablets (62.5/25) daily. For children over 40kg in weight, one MALARONE Tablet (250/100) once a day. Your doctor will choose the right dose for the child.

In order to prevent malaria, it is important that you take your MALARONE every day. Start taking the tablets 1 or 2 days before travelling to a country (or countries) where you are at risk of getting malaria. Continue daily dosing while you are there and for 7 days after leaving the country.

Whilst in a malarious area, use of personal protection such as permethrin impregnated bednets and topical insect repellents is also strongly recommended.

### **Treatment of Malaria**

**Adults:** Four MALARONE Tablets (250/100), once a day, for three days.

**Children (11-40kg):** Depending on the child's weight one, two or three MALARONE Tablets (250/100) once a day, for three days. For children over 40 kg in weight, four MALARONE tablets (250/100) once a day for three days. Your doctor will choose the right dose for the child.

### **How long to take it for Prevention of Malaria**

MALARONE should be taken 1 or 2 days before travelling to a country (or countries) where you are at risk of getting malaria, and continued daily while you are there and for 7 days after leaving the country.

### **Treatment of Malaria**

MALARONE should be taken for three days in a row.

Do not stop taking MALARONE, or change the dose without first checking with your doctor.

### **Use in children**

MALARONE is not recommended for the treatment of malaria in children less than 3 years of age.

### **If you take too much (overdose)**

Immediately telephone your doctor or Poisons Information Centre (0800 POISON 0800 764 766) for advice, if you think you or anyone else may have taken too many MALARONE tablets, even if there are no signs of discomfort or poisoning. You may need urgent medical attention.

Keep telephone numbers for these places handy.

If you are not sure what to do, contact your doctor or pharmacist.

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### **While you are taking MALARONE**

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#### **Things you must do**

Tell your doctor or pharmacist that you are taking MALARONE if you are about to be started on any new medicines.

Tell your doctor if you become pregnant or are trying to become pregnant.

Tell your doctor if, for any reason, you have not taken your medicine exactly as prescribed. Otherwise, your doctor may think it was not effective and change your treatment unnecessarily.

### **Things you must not do**

Do not change the dose of your MALARONE without first checking with your doctor.

Do not give this medicine to anyone else, even if their symptoms seem similar to yours.

### **Things to be careful of**

Be careful driving or operating machinery until you know how MALARONE affects you.

MALARONE generally does not cause any problems with your ability to drive a car or operate machinery.

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### **Side-Effects**

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**Check with your doctor as soon as possible if you have any problems while taking MALARONE, even if you do not think the problems are connected with the medicine or are not listed.**

Like other medicines, MALARONE can cause some side effects. If they occur, they are most likely to be minor and temporary. However, some may be serious and need medical attention.

The following side-effects have been reported in persons taking MALARONE or the active ingredients (atovaquone or proguanil). Most of

these have been mild and have not lasted very long:

- Loss of appetite, feeling sick (nausea) and/or being sick (vomiting), stomach pain, diarrhoea
- Mouth ulcers
- Rash or itching
- Headache, difficulty sleeping and dizziness
- Tiredness
- Inflammation of the liver (hepatitis), yellow discolouration of the skin or eyes (jaundice)
- 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
- Cough
- Fever
- Hair loss
- Skin rash, which may blister and look 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).
- Seeing or hearing things that are not there (hallucinations).

If you notice any of these symptoms contact a doctor urgently.

Sometimes MALARONE is associated with abnormal blood tests of liver function. If this does happen it is most likely a temporary change, as blood tests of liver function become normal after completing the treatment.

Other abnormal blood tests reported with MALARONE include:

- A reduction in the number of red blood cells (anaemia), white blood cells (neutropenia), or platelets (cells necessary for blood clotting).
- An increase in amylase, which is an enzyme produced by the pancreas.
- Low sodium (hyponatraemia).

**If you think you are having an allergic reaction to MALARONE, tell your doctor immediately or go to the Accident and Emergency department at your nearest hospital.**

**Symptoms of an allergic reaction usually include some or all of the following:**

- wheezing.
- swelling of the lips/mouth.
- difficulty in breathing.
- hay fever.
- lumpy rash ("hives").
- Fainting.

This is not the complete list of all possible side-effects. Others may occur in some people and there may be some side-effects not yet known.

**Tell your doctor if you notice anything else that is making you feel unwell, even if it is not on this list.**

**Do not be alarmed by this list of possible side effects. You may not experience any of them.**

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## **After taking MALARONE**

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### **Storage**

**Keep this medicine where young children cannot reach it.**

A locked cupboard at least one-and-a-half metres above the ground is a good place to store medicines.

**Keep MALARONE in a cool, dry place where it stays below 30°C.**

**Do not leave MALARONE in a car, on a window sill or in the bathroom.**

Heat, light and dampness can destroy some medicines.

**Keep MALARONE in its pack until it is time to take the tablets.**

### **Disposal**

**If your doctor tells you to stop taking**

**MALARONE, or the medicine has passed the expiry date, ask your pharmacist what to do with any medicine left over.**

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## **Product description**

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### ***What MALARONE looks like***

MALARONE Tablets (250/100) are round, bi-convex, pink, film-coated tablets, engraved on one side with "GX CM3"

MALARONE Junior Tablets (62.5/25) are round, bi-convex, pink, film-coated tablets, engraved on one side with "GX CG7".

MALARONE Tablets (250/100) and MALARONE Junior Tablets (62.5/25) are supplied in blister packs of 12 tablets.

### ***Ingredients***

Each MALARONE Tablet (250/100) contains the active ingredients atovaquone 250mg and proguanil hydrochloride 100mg.

Each MALARONE Junior Tablet (62.5/25) contains the active ingredients atovaquone 62.5mg and proguanil hydrochloride 25mg.

Each tablet also contains the inactive ingredients: Poloxamer 188, microcrystalline cellulose, low-substituted hydroxypropyl cellulose,

povidone K30, sodium starch glycollate, magnesium stearate, hypromellose, titanium dioxide, iron oxide red E172, macrogol 400, macrogol 8000.

### ***Manufacturer***

Your MALARONE is supplied by:

GlaxoSmithKline NZ  
Private Bag 106600  
Downtown, Auckland  
New Zealand

Ph: (09) 367 2900  
Fax: (09) 367 2910

### ***Further information***

Pharmaceutical companies are not in a position to give people individual diagnosis or medical advice. Your doctor or pharmacist is the best person to give you advice on the treatment of your condition. You may also be able to find general information about your disease and its treatment from books, for example in public libraries.

**Do not throw this leaflet away. You may need to read it again.**

The information provided applies only to MALARONE®.

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