

# MALARONE TABLETS & MALARONE JUNIOR TABLETS

## Consumer Medicine Information (CMI) summary

The information for MALARONE in this document applies to both MALARONE TABLETS and MALARONE JUNIOR TABLETS unless explicitly referenced.

The [full CMI](#) on the next page has more details. If you are worried about using this medicine, speak to your doctor or pharmacist.

### 1. Why am I taking MALARONE?

MALARONE contains the active ingredients atovaquone and proguanil hydrochloride. MALARONE is used to prevent or treat a certain type of malaria known as plasmodium falciparum malaria.

For more information, see Section [1. Why am I taking MALARONE?](#) in the full CMI.

### 2. What should I know before I take MALARONE?

Do not take if you or your child have ever had an allergic reaction to MALARONE or any of the ingredients listed at the end of the CMI.

**Talk to your doctor if you or your child have any other medical conditions, have severe kidney disease, experience a severe skin reaction, take any other medicines, or are pregnant or plan to become pregnant or are breastfeeding.**

For more information, see Section [2. What should I know before I take MALARONE?](#) in the full CMI.

### 3. What if I am taking other medicines?

Some medicines may interfere with MALARONE and affect how it works.

A list of these medicines is in Section [3. What if I am taking other medicines?](#) in the full CMI.

### 4. How do I take MALARONE?

- Prevention of malaria: adults and children over 40 kg take one MALARONE TABLETS once a day. Children 11 to 40 kg will depend on bodyweight. Take MALARONE 1 to 2 days before you visit a malaria area, whilst you are there and for 7 days afterwards.
- Treatment of malaria: adults and children over 40 kg take four MALARONE TABLETS once a day. Children 11 to 40 kg will depend on bodyweight. Take MALARONE for 3 consecutive days.
- Take with food or a milky drink. The tablets can be crushed and mixed with milk immediately before serving for children.

More instructions can be found in Section [4. How do I take MALARONE?](#) in the full CMI.

### 5. What should I know while taking MALARONE?

|                             |                                                                                                                                                                                                                                                                                               |
|-----------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Things you should do        | <ul style="list-style-type: none"><li>• Remind any doctor, dentist or pharmacist you visit that you are taking MALARONE.</li><li>• Use of personal protection such as permethrin impregnated bed nets and topical insect repellants is strongly recommended when in malarial areas.</li></ul> |
| Things you should not do    | <ul style="list-style-type: none"><li>• Do not take MALARONE to treat malaria caused by other types of parasites.</li></ul>                                                                                                                                                                   |
| Driving or using machines   | <ul style="list-style-type: none"><li>• Be careful before you drive, ride a bike or use any machines or tools until you know how MALARONE affects you.</li></ul>                                                                                                                              |
| Looking after your medicine | <ul style="list-style-type: none"><li>• Store MALARONE below 30°C. Keep the tablets in the pack until it is time to take them.</li></ul>                                                                                                                                                      |

For more information, see Section [5. What should I know while taking MALARONE?](#) in the full CMI.

### 6. Are there any side effects?

Side effects which have been reported with the use of MALARONE include: diarrhoea, vomiting, feeling sick (nausea), abdominal pain, cough, vision or hearing disturbances, decreased appetite, headache, insomnia (difficulty sleeping), fatigue (feeling tired), yellow discolouration of skin or eyes (jaundice), inflammation of blood vessels, dizziness, anxiety, depression, mental health problems and fever. Severe skin reactions have also been reported (including red rash with blisters, peeling skin).

For more information, including what to do if you have any side effects, see Section [6. Are there any side effects?](#) in the full CMI.

# MALARONE TABLETS

## MALARONE JUNIOR TABLETS

Active ingredients: atovaquone and proguanil hydrochloride

### Consumer Medicine Information (CMI)

The information for MALARONE in this document applies to both MALARONE TABLETS and MALARONE JUNIOR TABLETS unless explicitly referenced.

This leaflet provides important information about using MALARONE. **You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about using MALARONE.**

Where to find information in this leaflet:

1. [Why am I taking MALARONE?](#)
2. [What should I know before I take MALARONE?](#)
3. [What if I am taking other medicines?](#)
4. [How do I take MALARONE?](#)
5. [What should I know whilst taking MALARONE?](#)
6. [Are there any side effects?](#)
7. [Product details](#)

### 1. Why am I taking MALARONE?

MALARONE contains the active ingredients atovaquone and proguanil hydrochloride. MALARONE belongs to a group of medicines called antimalarials.

MALARONE is used to prevent or treat the type of malaria known as *Plasmodium falciparum* malaria. *Plasmodium falciparum* belongs to one particular family of the malaria parasites. MALARONE works by killing this parasite.

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.

### 2. What should I know before I take MALARONE?

#### Warnings

Do not take MALARONE if:

- you are allergic to either atovaquone or proguanil hydrochloride, or any of the ingredients listed at the end of this leaflet.
- Always check the ingredients to make sure you can use this medicine.
- you have severe kidney disease.

#### Check with your doctor if you:

- have any other medical conditions.
- take any medicines for any other condition.
- currently have diarrhoea.
- have any kidney problems.
- have had severe skin reactions with MALARONE
- have been treated for malaria caused by *Plasmodium falciparum* in the past and it has occurred again.
- are an adult who weighs less than 40kg.

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them. See additional information under Section 6. [Are there any side effects?](#)

#### Severe skin reactions

MALARONE can cause severe skin reactions. You must look out for certain symptoms whilst you or your child is taking MALARONE to reduce the risk of any problems. If you or your child experiences any signs or symptoms of severe skin reactions, stop taking MALARONE and contact your doctor immediately.

#### Pregnancy and breastfeeding

Check with your doctor if you are pregnant or intend to become pregnant.

Talk to your doctor if you are breastfeeding or intend to breastfeed.

#### Use in children

- MALARONE JUNIOR TABLETS should be used only in children weighing more than 11 kg.
- MALARONE is not recommended for the treatment of malaria in children under the age of 3.

### 3. What if I am taking other medicines?

Tell your doctor or pharmacist if you are taking any other medicines, including any medicines, vitamins or supplements that you buy without a prescription from your pharmacy, supermarket or health food shop.

**Some medicines may interfere with MALARONE and affect how it works.**

- Warfarin, a medicine used to thin the blood.
- Antibiotic medicines such as tetracycline, rifabutin and cephalosporin used to treat bacterial infections.
- Metoclopramide, a medicine used to treat nausea (feeling sick) and vomiting.
- Rifampicin, a medicine used to treat tuberculosis.
- Paracetamol and opiates, medicines used to treat pain.

- Benzodiazepines, used to treat depression, anxiety, insomnia.
- Aciclovir, an antiviral medicine.
- Indinavir and efavirenz, medicines used to treat HIV.

**Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect MALARONE.**

## 4. How do I take MALARONE?

### PREVENTION OF MALARIA

#### How much to take

Adults and children over 40 kg:

- Take one MALARONE TABLETS once a day.

Children 11 to 40 kg:

- Depending on bodyweight, your child will take one, two or three MALARONE JUNIOR TABLETS once a day.

#### When to take

- Begin taking this medicine 1 to 2 days before entering a place where you are at risk of getting malaria.
- Continue to take MALARONE each day whilst you are there and then for 7 days after you have left.

### TREATMENT OF MALARIA

#### How much to take

Adults and children over 40 kg:

- Take four MALARONE TABLETS once a day.

Children 11 to 40 kg:

- Depending on bodyweight, your child will take one, two or three MALARONE TABLETS once a day.

#### When to take

- Take MALARONE TABLETS for 3 days in a row.

#### How to take MALARONE

- Swallow the tablet whole with food or a milky drink.
- For children who find the tablets difficult to swallow, they may be crushed and mixed with food or a milky drink right 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.

#### If you forget to take MALARONE

MALARONE should be taken regularly at the same time each day.

**If it is almost time for your next dose, skip the dose you missed and take your next dose when you are meant to.**

**Do not take a double dose to make up for the dose you missed.**

### If you take too much MALARONE

If you think that you or anyone else have taken too much MALARONE, you may need urgent medical attention.

#### You should immediately:

- phone the Poisons Information Centre (by calling 13 11 26), or
- contact your doctor, or
- go to the Emergency Department at your nearest hospital.

**You should do this even if there are no signs of discomfort or poisoning.**

## 5. What should I know whilst taking MALARONE?

### Things you should do

- When in a known malarial area, use of personal protection such as permethrin impregnated bed nets and topical insect repellants is strongly recommended.

### Call your doctor straight away if you:

- feel the symptoms of your malaria have returned after taking MALARONE.

Remind any doctor, dentist or pharmacist you visit that you are taking MALARONE.

### Things you should not do

- Do not take MALARONE to prevent or treat malaria caused by other types of parasites.

### Driving or using machines

**Be careful before you drive, ride a bike or use any machines or tools until you know how MALARONE affects you.**

### Looking after your medicine

- Store MALARONE below 30°C.

Follow the instructions on the carton on how to take care of your medicine properly.

Store it in a cool dry place away from moisture, heat or sunlight; for example, do not store it:

- in the bathroom or near a sink, or
- in the car or on window sills.

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

### Getting rid of any unwanted medicine

If you no longer need to use this medicine or it is out of date, take it to any pharmacy for safe disposal.

Do not use this medicine after the expiry date.

## 6. Are there any side effects?

All medicines can have side effects. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention.

See the information below and, if you need to, ask your doctor or pharmacist if you have any further questions about side effects.

### Less serious side effects

| Less serious side effects                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 | What to do                                                                                         |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------|
| <b>Gastrointestinal related</b> <ul style="list-style-type: none"> <li>diarrhoea</li> <li>stomach pain</li> <li>vomiting, feeling sick (nausea)</li> <li>abdominal pain</li> <li>indigestion</li> <li>mouth ulcers</li> </ul> <b>Skin related</b> <ul style="list-style-type: none"> <li>rash, itching</li> <li>hair loss</li> </ul> <b>Chest and lung related</b> <ul style="list-style-type: none"> <li>cough</li> </ul> <b>Eye related</b> <ul style="list-style-type: none"> <li>vision disturbances</li> </ul> <b>Metabolism and food related</b> <ul style="list-style-type: none"> <li>decreased appetite</li> </ul> <b>Nervous system related</b> <ul style="list-style-type: none"> <li>headache</li> <li>insomnia (difficulty sleeping)</li> <li>fatigue (feeling tired)</li> <li>vivid or strange dreams</li> <li>dizziness</li> </ul> <b>General disorders and administration site conditions</b> <ul style="list-style-type: none"> <li>fever</li> </ul> <b>Mental health related</b> <ul style="list-style-type: none"> <li>feeling of panic</li> <li>crying</li> <li>nightmares</li> </ul> | <b>Speak to your doctor if you have any of these less serious side effects and they worry you.</b> |

### Serious side effects

| Serious side effects                                                                                                                                                                                                                                                                                                                                                                            | What to do                                                                                                                                                  |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>Liver and gallbladder related</b> <ul style="list-style-type: none"> <li>yellowing of the skin or eyes (jaundice)</li> </ul> <b>Skin related</b> <ul style="list-style-type: none"> <li>inflammation of the blood vessels which may be visible on the skin as red or purple raised spots (vasculitis)</li> <li>widespread red rash with blisters that may include peeling of skin</li> </ul> | <b>Call your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you notice any of these serious side effects.</b> |

| Serious side effects                                                                                                                                                                                                                                                                                                                                                                       | What to do |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------|
| <ul style="list-style-type: none"> <li>severe skin reactions such as flu-like symptoms with a rash, fever, swollen glands and abnormal blood test results</li> </ul> <b>Mental health related</b> <ul style="list-style-type: none"> <li>seeing or hearing things that aren't there (hallucinations)</li> <li>depression</li> <li>anxiety</li> <li>other mental health problems</li> </ul> |            |

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).

**Tell your doctor or pharmacist if you notice anything else that may be making you feel unwell.**

Other side effects not listed here may occur in some people.

### Reporting side effects

After you have received medical advice for any side effects you experience, you can report side effects to the Therapeutic Goods Administration online at [www.tga.gov.au/reporting-problems](http://www.tga.gov.au/reporting-problems). By reporting side effects, you can help provide more information on the safety of this medicine.

**Always make sure you speak to your doctor or pharmacist before you decide to stop taking any of your medicines.**

## 7. Product details

This medicine is only available with a doctor's prescription.

### What MALARONE contains

|                                                 |                                                                                                                                     |
|-------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------|
| <b>Active ingredient (main ingredient)</b>      | atovaquone<br>proguanil hydrochloride                                                                                               |
| <b>Other ingredients (inactive ingredients)</b> | hypromellose<br>hypromellose<br>iron oxide red<br>macrogol 400<br>macrogol 8000<br>magnesium stearate<br>microcrystalline cellulose |

|  |                                                                       |
|--|-----------------------------------------------------------------------|
|  | poloxamer<br>povidone<br>sodium starch glycollate<br>titanium dioxide |
|--|-----------------------------------------------------------------------|

**Do not take this medicine if you are allergic to any of these ingredients.**

### **What MALARONE looks like**

MALARONE TABLETS are round, biconvex, pink film-coated tablets, branded "GX CM3" (AUST R 61100).

MALARONE TABLETS are available in packs of 12 or 24 tablets.

MALARONE JUNIOR TABLETS are round, biconvex, pink film-coated tablets, branded "GX CG7" (AUST R 92855).

MALARONE JUNIOR TABLETS are available in packs of 12, 24 or 60 tablets.

Not all pack sizes and presentations may be marketed in Australia.

### **Who distributes MALARONE**

GlaxoSmithKline Australia Pty Ltd

Level 4, 436 Johnston Street,

Abbotsford, Victoria, 3067

Phone: 1800 033 109

[www.gsk.com.au](http://www.gsk.com.au)

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