Malarone(R) Tablets (250/100) Malarone(R) Junior Tablets (62.5/25)

(Atovaquone and Proguanil Hydrochloride)

Consumer Medicine Information

What is in this leaflet?

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 expected benefits of you taking Malarone against the risks this medicine could 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.

What is Malarone used for?

Malarone belongs to a broad group of medicines called antimalarials.

It contains in one tablet a mixture of two antimalarial medicines which work well when taken together. One medicine is atovaquone and the other is proguanil hydrochloride.

Malarone is used to prevent or treat the type of malaria infection known as Plasmodium falciparum malaria. Plasmodium falciparum belongs to one particular family of malaria parasites. It affects the blood and liver. Malarone works by killing this parasite.

Malarone is not addictive.

Before you take Malarone

Do not take if:

You must not take Malarone if:

* you have ever had an allergic reaction to atovaquone (Wellvone (TM)) or proguanil hydrochloride (Paludrine), or any of the ingredients listed at the end of this leaflet (See "Ingredients").
* **the expiry date (EXP) printed on the pack has passed.**
* **the packaging is torn or shows signs of tampering**

Tell your doctor if:

You must tell your doctor if:

* **you are allergic to foods, dyes, preservatives or any other medicines.**
* **in the past Malarone has been ineffective for you.**
* **after taking Malarone, your symptoms of malaria have returned after improving for a time.**
* **you have diarrhoea (loose bowel motions). This may interfere with the absorption of Malarone.**
* **you have kidney problems.**
* **you are taking any medicines containing warfarin, rifampicin, rifabutin, tetracycline, metoclopramide or indinavir.**
* **you are taking any other medicines, including medicines you buy without a prescription.**
* **you are breastfeeding, pregnant or trying to become pregnant.**

How do I take Malarone?

How much to take

Take Malarone as directed by your doctor or pharmacist.

Prevention of malaria:

Adults:

One Malarone Tablet (250/100) daily.

Children (11-40 Kg):

Depending on the child's weight, one, two or three Malarone Junior Tablets (62.5/25) daily. For children over 40 kg 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 it 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.

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 (11-40 Kg):

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 to take it

Swallow each tablet whole. Malarone works better if you take it with food or a milky drink and at about the same time each day.

If you vomit within one hour of taking Malarone take another dose as soon as you can. In the event of diarrhoea, normal dosing should be continued and personal protection should be used (repellants, bednets).

How long to take it for

Prevention of malaria:

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

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.

What do I do if I take too much? (Overdose)

Immediately telephone your doctor or Poisons Information Centre (telephone 131126) for advice, if you think you or anyone else may have taken too much Malarone, even if there are no signs of discomfort or poisoning.

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

While you are taking Malarone

Things you must do

Tell your doctor if, for any reason, you have not taken your medicine exactly as directed.

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

Otherwise, your doctor may think that it was not working as it should and change your treatment unnecessarily.

Things you must not do

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

Do not use Malarone to treat any other complaints unless your doctor says to.

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. However, as with many other medicines, Malarone may cause headache in some people.

What are the side effects?

Check with your doctor as soon as possible if you think you are experiencing any side effects or allergic reactions due to taking Malarone, even if the problem is not listed below.

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 in sleeping, vivid or strange dreams and dizziness
* Tiredness and loss of energy
* 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.

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).

STOP taking Malarone and seek medical attention immediately if you experience any of the following severe allergy symptoms after taking Malarone. Although they are rare, these symptoms could be serious:

* Sudden wheezing, tightness of the chest or throat, or difficulty breathing
* Swollen eyelids, face, lips, tongue or other part of the body
* Widespread rash.

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

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

How do I store Malarone?

Keep this medicine where children cannot reach it, such as in a locked cupboard.

Keep Malarone in a cool, dry place where it stays below 30 degrees C.

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

Keep Malarone in its blister pack until it is time to take the tablets.

Return any unused or expired medicine to your pharmacist.

Product description

What Malarone looks like

Malarone Tablets (250/100) are round, pink and film-coated, and are engraved with "GX CM3".

Malarone Tablets (250/100) are supplied in blister packs of 12 tablets.

Malarone Junior Tablets (62.5/25) are round, pink and film-coated, and are engraved with "GX CG7".

Malarone Junior Tablets (62.5/25) are supplied in blister packs of 12 tablets.

Ingredients

Malarone Tablets (250/100) contain the active ingredients, atovaquone 250 mg and proguanil hydrochloride 100 mg.

Malarone Junior Tablets (62.5/25) contain the active ingredients, atovaquone 62.5 mg and proguanil hydrochloride 25 mg.

Each tablet also contains hydroxypropylcellulose, microcrystalline cellulose, povidone K30, sodium starch glycollate, macrogol 400, magnesium stearate, macrogol 8000, poloxamer 188 and pink colour concentrate OY-S-24972.

Supplier

Your Malarone is supplied by:
GlaxoSmithKline Australia Pty Ltd
1061 Mountain Highway
Boronia
Victoria, 3155
Australia.

Where to go for further information

Pharmaceutical companies are not in a position to give people an 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.

This leaflet was prepared on 16 April 2008.

The information provided applies only to: Malarone(R).

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(TM) Wellvone is a trademark of the GlaxoSmithKline Group of Companies.

Malarone Tablets:
AUST R 61100.
Malarone Junior Tablets:
AUST R 92855

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