

Promozio[®] 250/100

(Atovaquone and Proguanil Hydrochloride)

Consumer Medicine Information

What is in this leaflet

Please read this leaflet carefully before you take Promozio 250/100.

This leaflet answers some common questions about Promozio 250/100. 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 Promozio 250/100 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 Promozio 250/100 used for?

Promozio 250/100 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.

Promozio 250/100 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. Promozio 250/100 works by killing this parasite.

Promozio 250/100 is not addictive.

Before you take Promozio 250/100

Do not take it:

You must not take Promozio 250/100 if:

- you have ever had an allergic reaction to atovaquone (Wellvone[™]) 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 Promozio 250/100 has been ineffective for you.
- after taking Promozio 250/100, your symptoms of malaria have returned after improving for a time.
- you have diarrhoea (loose bowel motions). This may interfere with the absorption of Promozio 250/100.
- 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 Promozio 250/100?

How much to take

Take Promozio 250/100 as directed by your doctor or pharmacist.

Prevention of malaria:

Adults:

One Promozio 250/100 tablet daily.

In order to prevent malaria, it is important that you take your Promozio 250/100 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 Promozio 250/100 tablets, once a day, for three days.

How to take it

Swallow each tablet whole.

Promozio 250/100 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 Promozio 250/100 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:

Promozio 250/100 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:

Promozio 250/100 should be taken for three days in a row.

Do not stop taking Promozio 250/100, or change the dose without first checking with your doctor.

Use in children

Promozio 250/100 is not recommended for the treatment of malaria in children.

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 Promozio 250/100, 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 Promozio 250/100

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 Promozio 250/100 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 Promozio 250/100 affects you.

Promozio 250/100 generally does not cause any problems with your ability to drive a car or operate machinery.

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 Promozio 250/100, even if the problem is not listed below.

Like other medicines, Promozio 250/100 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 Promozio 250/100 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
- 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.

- Seeing or hearing things that are not there (hallucinations).

Sometimes Promozio 250/100 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 Promozio 250/100 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 Promozio 250/100 and seek medical attention immediately if you experience any of the following severe allergy symptoms after taking Promozio 250/100. 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 Promozio 250/100?

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

Keep Promozio 250/100 in a cool, dry place where it stays below 25°C.

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

Keep Promozio 250/100 in its blister pack until it is time to take the tablets.

Return any unused or expired medicine to your pharmacist.

Product description

What Promozio 250/100 looks like

Promozio 250/100 tablets are pinkish brown to brown coloured, round with '404' engraved on one side and 'G' engraved on the other side. Promozio 250/100 tablets are supplied in blister packs of 12 tablets.

Ingredients

Promozio 250/100 tablets contain the active ingredients, atovaquone 250 mg and proguanil hydrochloride 100 mg.

Each tablet also contains microcrystalline cellulose, hydroxypropylcellulose, sodium starch glycollate, poloxamer , povidone, silica - colloidal

anhydrous, magnesium stearate, and Opadry complete film coating system 03C86943 BROWN.

Supplier

Promozio 250/100 is supplied by:

Australia:

sanofi-aventis australia Pty Ltd

Building D, 12-24 Talavera Road

Macquarie Park NSW 2113

Australia

Tel: 1800 829 468

New Zealand:

sanofi-aventis new zealand limited

Level 8, 56 Cawley St

Ellerslie, Auckland

New Zealand

Tel: 0800 727 838

AUST R number

AUST R 259969

Date of preparation

27 June 2016

promozio-piv1.2-27Jun16