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 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.

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
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 discoloration
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 25ºC.
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

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