

AtovaquoPro Lupin 250/100 and AtovaquoPro Lupin 62.5/25

Consumer Medicine Information (CMI) summary

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 using AtovaquoPro Lupin 250/100 and AtovaquoPro Lupin 62.5/25?

This product contains the active ingredients atovaquone and proguanil hydrochloride, which are used to prevent or treat the type of malaria infection known as *Plasmodium falciparum* malaria.

For more information, see Section [1. Why am I using AtovaquoPro Lupin 250/100 and AtovaquoPro Lupin 62.5/25?](#) in the full CMI.

2. What should I know before I use AtovaquoPro Lupin 250/100 and AtovaquoPro Lupin 62.5/25?

Do not use if you have ever had an allergic reaction to atovaquone and proguanil or any of the ingredients listed at the end of the CMI.

Talk to your doctor if you have any other medical conditions, 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 use AtovaquoPro Lupin 250/100 and AtovaquoPro Lupin 62.5/25?](#) in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with AtovaquoPro Lupin 250/100 and AtovaquoPro Lupin 62.5/25 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 use AtovaquoPro Lupin 250/100 and AtovaquoPro Lupin 62.5/25?

Take this medicine as directed by your doctor or pharmacist.

More instructions can be found in Section [4. How do I use AtovaquoPro Lupin 250/100 and AtovaquoPro Lupin 62.5/25?](#) in the full CMI.

5. What should I know while using AtovaquoPro Lupin 250/100 and AtovaquoPro Lupin 62.5/25?

Things you should do	<ul style="list-style-type: none">Remind any doctor, dentist, or pharmacist you visit that you are using AtovaquoPro Lupin 250/100 and AtovaquoPro Lupin 62.5/25 or if you are about to be started on any new medicine.Tell your doctor if, for any reason, you have not taken your medicine exactly as directed.
Things you should not do	<ul style="list-style-type: none">Do not give this medicine to anyone else, even if their symptoms seem similar to yours.Do not use this medicine to treat any other complaints unless your doctor says to.
Driving or using machines	<ul style="list-style-type: none">Be careful driving or operating machinery until you know how AtovaquoPro Lupin 250/100 and AtovaquoPro Lupin 62.5/25 affects you.
Looking after your medicine	<ul style="list-style-type: none">Store in cool, dry place where it stays below 25°C.Store in the original package.

For more information, see Section [5. What should I know while using AtovaquoPro Lupin 250/100 and AtovaquoPro Lupin 62.5/25?](#) in the full CMI.

6. Are there any side effects?

Common side effects include loss of appetite, feeling sick or being sick, stomach pain, diarrhoea, mouth ulcers, rash or itching, headache, vivid dreams, dizziness, tiredness, cough and fever. Sudden wheezing, tightness of the chest or throat, or difficulty in breathing, swollen eyelids, face, lips, tongue or other part of the body, and widespread rash are the serious side effects.

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.

AtovaquoPro Lupin 250/100 and AtovaquoPro Lupin 62.5/25

Active ingredient(s): *atovaquone and proguanil hydrochloride*

Consumer Medicine Information (CMI)

This leaflet provides important information about using AtovaquoPro Lupin 250/100 and AtovaquoPro Lupin 62.5/25. **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 AtovaquoPro Lupin 250/100 and AtovaquoPro Lupin 62.5/25.**

Where to find information in this leaflet:

- [1. Why am I using AtovaquoPro Lupin 250/100 and AtovaquoPro Lupin 62.5/25?](#)
- [2. What should I know before I use AtovaquoPro Lupin 250/100 and AtovaquoPro Lupin 62.5/25?](#)
- [3. What if I am taking other medicines?](#)
- [4. How do I use AtovaquoPro Lupin 250/100 and AtovaquoPro Lupin 62.5/25?](#)
- [5. What should I know while using AtovaquoPro Lupin 250/100 and AtovaquoPro Lupin 62.5/25?](#)
- [6. Are there any side effects?](#)
- [7. Product details](#)

1. Why am I using AtovaquoPro Lupin 250/100 and AtovaquoPro Lupin 62.5/25?

This product contains the active ingredients **atovaquone and proguanil hydrochloride**. AtovaquoPro Lupin 250/100 and AtovaquoPro Lupin 62.5/25 belongs to a broad group of medicines called antimalarials.

AtovaquoPro Lupin 250/100 and AtovaquoPro Lupin 62.5/25 are used to prevent or treat the type of malaria infection known as *Plasmodium falciparum* malaria.

Plasmodium falciparum belongs to a particular family of malaria parasites. It affects the blood and liver.

AtovaquoPro Lupin 250/100 and AtovaquoPro Lupin 62.5/25 work by killing this parasite.

AtovaquoPro Lupin 250/100 and AtovaquoPro Lupin 62.5/25 are not addictive.

2. What should I know before I use AtovaquoPro Lupin 250/100 and AtovaquoPro Lupin 62.5/25?

Warnings

Do not use AtovaquoPro Lupin 250/100 and AtovaquoPro Lupin 62.5/25 if:

- you are allergic to 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.
- the expiry date (EXP) printed on the pack has passed.
- the packaging is torn or shows signs of tampering

Check with your doctor if:

- you have any other medical conditions like:
 - you are allergic to foods, dyes, preservatives or any other medicines.
 - diarrhoea (loose bowel motions). This may interfere with the absorption of AtovaquoPro Lupin 250/100 and AtovaquoPro Lupin 62.5/25.
 - kidney problems.
- you take any medicines for any other condition like:
 - any medicines containing warfarin, rifampicin, rifabutin, tetracycline, metoclopramide, efavirenz or indinavir.
 - any other medicines, including medicines you buy without a prescription.
- in the past AtovaquoPro Lupin 250/100 and AtovaquoPro Lupin 62.5/25 have been ineffective for you.
- after taking AtovaquoPro Lupin 250/100 and AtovaquoPro Lupin 62.5/25, your symptoms of malaria have returned after improving for a time.

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?](#)

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.

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.

Medicines that may reduce the effect of AtovaquoPro Lupin 250/100 or AtovaquoPro Lupin 62.5/25:

- efavirenz, tetracycline, metoclopramide, rifampicin and rifabutin.

The effect of medicines that may be increased by AtovaquoPro Lupin 250/100 or AtovaquoPro Lupin 62.5/25 include:

- warfarin and other coumarin based anticoagulants.

The effect of medicines that may be decreased by AtovaquoPro Lupin 250/100 or AtovaquoPro Lupin 62.5/25 include:

- indinavir.

Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect AtovaquoPro Lupin 250/100 and AtovaquoPro Lupin 62.5/25.

4. How do I use AtovaquoPro Lupin 250/100 and AtovaquoPro Lupin 62.5/25?

How much to take

Take AtovaquoPro Lupin 250/100 and AtovaquoPro Lupin 62.5/25 as directed by your doctor or pharmacist.

Prevention of Malaria

In order to prevent malaria, it is important that you take your AtovaquoPro Lupin 250/100 or AtovaquoPro Lupin 62.5/25 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.

Adults:

One (1) AtovaquoPro Lupin 250/100 tablet daily.

Children:

Depending on the child's weight, one, two or three (1, 2 or 3) AtovaquoPro Lupin 62.5/25 tablets daily. For children over 40 kg in weight, one (1) AtovaquoPro Lupin 250/100 tablet once a day.

Your doctor will choose the right dose for the child.

Treatment of Malaria

Follow the instructions provided and use AtovaquoPro Lupin 250/100 or AtovaquoPro Lupin 62.5/25 until your doctor tells you to stop.

Adults:

Four (4) AtovaquoPro Lupin 250/100 tablets once a day for three (3) days.

Children:

Depending on the child's weight, one, two or three (1, 2 or 3) AtovaquoPro Lupin 250/100 tablets once a day for three (3) days. For children over 40 kg in weight, four (4) AtovaquoPro Lupin 250/100 tablets once a day for three (3) days.

Your doctor will choose the right dose for the child.

How to take

Swallow each tablet whole. AtovaquoPro Lupin 250/100 and AtovaquoPro Lupin 62.5/25 work better if you take them with food or a milky drink at about the same time each day.

For children who find the tablet(s) difficult to swallow, the tablet(s) may be crushed and added to a small amount of milk, just before being taken.

If you vomit within one hour of taking AtovaquoPro Lupin 250/100 or AtovaquoPro Lupin 62.5/25, take another dose as soon as you can. In the event of diarrhoea, normal dosing should be continued, and personal protection should be used (repellents, bednets).

When to take AtovaquoPro Lupin 250/100 and AtovaquoPro Lupin 62.5/25

Take your medicine with food or a milky drink at about the same time each day.

How long to take AtovaquoPro Lupin 250/100 and AtovaquoPro Lupin 62.5/25 for

Prevention of Malaria

AtovaquoPro Lupin 250/100 and AtovaquoPro Lupin 62.5/25 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

AtovaquoPro Lupin 250/100 and AtovaquoPro Lupin 62.5/25 should be taken for three (3) days in a row.

Do not stop taking AtovaquoPro Lupin 250/100 or AtovaquoPro Lupin 62.5/25, or change the dose without first checking with your doctor.

Use in Children

AtovaquoPro Lupin 250/100 and AtovaquoPro Lupin 62.5/25 are not recommended for the treatment of malaria in children less than 3 years of age.

If you forget to take AtovaquoPro Lupin 250/100 and AtovaquoPro Lupin 62.5/25

AtovaquoPro Lupin 250/100 and AtovaquoPro Lupin 62.5/25 should be used regularly at the same time each day. If you miss your dose at the usual time, take another as soon as possible. Then go on as before.

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 AtovaquoPro Lupin 250/100 and AtovaquoPro Lupin 62.5/25

If you think that you have taken too much AtovaquoPro Lupin 250/100 or AtovaquoPro Lupin 62.5/25, 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 while using AtovaquoPro Lupin 250/100 and AtovaquoPro Lupin 62.5/25?

Things you should 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.

If you are about to start taking any new medicines containing warfarin, rifampicin, rifabutin, tetracycline, metoclopramide, efavirenz or indinavir or you any other medicines that you are about to buy without a prescription, tell your doctor and pharmacist that you are taking AtovaquoPro Lupin 250/100 or AtovaquoPro Lupin 62.5/25.

Tell your doctor if you notice any symptoms of malaria or your symptoms of malaria have returned after improving for a time.

Call your doctor straight away if you:

See or hear things that are not there (hallucinations).

Experience any of the following severe allergy symptoms after taking AtovaquoPro Lupin 250/100 or AtovaquoPro Lupin 62.5/25. Although they are rare, these symptoms could be serious:

- sudden wheezing, tightness of the chest or throat, or difficulty in breathing;
- swollen eyelids, face, lips, tongue, or other part of the body; or
- widespread rash.

Remind any doctor, dentist or pharmacist you visit that you are using AtovaquoPro Lupin 250/100 or AtovaquoPro Lupin 62.5/25.

Things you should not do

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

Do not use AtovaquoPro Lupin 250/100 or AtovaquoPro Lupin 62.5/25 to treat any other complaints unless your doctor says to.

Driving or using machines

Be careful before you drive or use any machines or tools until you know how AtovaquoPro Lupin 250/100 and AtovaquoPro Lupin 62.5/25 affects you.

AtovaquoPro Lupin 250/100 and AtovaquoPro Lupin 62.5/25 generally do not cause any problems with your ability to drive a car or operate machinery.

Looking after your medicine

Keep AtovaquoPro Lupin 250/100 and AtovaquoPro Lupin 62.5/25 in the blister pack until it is time to take the tablets.

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 where the temperature stays below 25°C. For example, do not store it:

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

Heat and dampness can destroy some medicines.

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.

Sometimes this medicine 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 this medicine 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).

Less serious side effects

Less serious side effects	What to do
<ul style="list-style-type: none">• Loss of appetite, feeling sick (nausea) and/or being sick (vomiting), stomach pain, diarrhoea.	Speak to your doctor if you have any of these less

<ul style="list-style-type: none"> • 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). 	serious side effects and they worry you.
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Serious side effects

Serious side effects	What to do
<ul style="list-style-type: none"> • Severe allergy with following symptoms: <ul style="list-style-type: none"> ○ sudden wheezing, tightness of the chest or throat, or difficulty in breathing; ○ swollen eyelids, face, lips, tongue or other part of the body; or ○ widespread rash. • Seeing or hearing things that are not there (hallucinations). 	<p>STOP taking AtovaquoPro Lupin 250/100 or AtovaquoPro Lupin 62.5/25. 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.</p>

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. 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 AtovaquoPro Lupin 250/100 and AtovaquoPro Lupin 62.5/25 contains

Active ingredient (main ingredient)	Atovaquone Proguanil hydrochloride
Other ingredients (inactive ingredients)	Hyprolose Microcrystalline cellulose Povidone Sodium starch glycollate Macrogol 400 Magnesium stearate Macrogol 8000 Poloxamer Colloidal anhydrous silica Iron oxide red
Potential allergens	Not applicable

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

What AtovaquoPro Lupin 250/100 and AtovaquoPro Lupin 62.5/25 looks like

AtovaquoPro Lupin 250/100 tablets are: Pink, round, biconvex, film-coated tablets, debossed with 'H' on one side and '175' on the other side.

AtovaquoPro Lupin 62.5/25 tablets are: Pink, round, biconvex, film-coated tablets, debossed with 'I' on one side and '11' on the other side.

Who distributes AtovaquoPro Lupin 250/100 and AtovaquoPro Lupin 62.5/25

Generic Health Pty Ltd
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