

Package leaflet: Information for the user

Atovaquone/Proguanil Hydrochloride 62.5 mg/25 mg film-coated tablets atovaquone/proguanil hydrochloride

Read all of this leaflet carefully before you start using this medicine because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for your child only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If your child gets any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet (See section 4).

What is in this leaflet:

1. What Atovaquone/Proguanil Hydrochloride is and what it is used for
2. What you need to know before you use Atovaquone/Proguanil Hydrochloride
3. How to use Atovaquone/Proguanil Hydrochloride
4. Possible side effects
5. How to store Atovaquone/Proguanil Hydrochloride
6. Contents of the pack and other information

1. What Atovaquone/Proguanil Hydrochloride is and what it is used for

Atovaquone/Proguanil Hydrochloride belongs to a group of medicines called *antimalarials*. It contains two active ingredients, atovaquone and proguanil hydrochloride.

Atovaquone/Proguanil Hydrochloride has two uses:

- **to prevent malaria** (for children weighing between 11kg and 40kg)
- **to treat malaria** (for children weighing between 5kg and 11kg)

Dosage instructions for each use are in Section 3, *How to give Atovaquone/Proguanil Hydrochloride*.

Although this medicine is usually used for children and teenagers, it can be prescribed for adults weighing less than 40kg.

Malaria is spread by the bite of an infected mosquito, which passes the malaria parasite (*Plasmodium falciparum*) into the bloodstream. Atovaquone/Proguanil Hydrochloride prevents malaria by killing this parasite. For people who are already infected with malaria, Atovaquone/Proguanil Hydrochloride also kills these parasites.

Protect your child from catching malaria

People of any age can get malaria. It is a serious disease, but is preventable.

As well as giving Atovaquone/Proguanil Hydrochloride, it is very important that you also take steps to avoid being bitten by mosquitoes.

- **Use insect repellent on exposed areas of the skin**
- **Wear light coloured clothing that covers most of the body**, especially after sunset as this is the time when mosquitoes are most active
- **Sleep in a screened room** or under a mosquito net impregnated with insecticide
- **Close windows and doors at sunset**, if they are not screened
- **Consider using an insecticide** (mats, spray, plug-ins) to clear a room of insects or to deter mosquitoes from entering the room.

If you need further advice, talk to your doctor or pharmacist.

It is still possible to get malaria after taking the necessary precautions. Some types of malaria infection take a long time to cause symptoms, so the illness may not start until several days, weeks or even months after returning from abroad.

See a doctor immediately if your child gets symptoms after returning from abroad, such as high temperature, headache, shivering and tiredness.

2. What you need to know before you use Atovaquone/Proguanil Hydrochloride

Do not take Atovaquone/Proguanil Hydrochloride:

- **if your child is allergic** to atovaquone, proguanil hydrochloride or any of the other ingredients of this medicine (listed in section 6).
- **for preventing malaria, if your child has severe kidney disease.**

Tell your doctor if either of these apply to your child.

Take special care with Atovaquone/Proguanil Hydrochloride

Talk to your doctor or pharmacist before you give Atovaquone/Proguanil Hydrochloride to your child if:

- your child has severe kidney disease
- your child is being treated for Malaria and weighs less than 5 kg or is given Atovaquone/Proguanil Hydrochloride to prevent Malaria and weighs less than 11 kg.

Tell your doctor or pharmacist if any of these applies to your child.

If any of the above applies to your child, talk to your doctor, before your child starts taking this medicine.

Other medicines and Atovaquone/Proguanil Hydrochloride

Tell your doctor or pharmacist if your child is taking, has recently taken or might take any other medicine, including medicines bought without prescription.

Some medicines can affect the way Atovaquone/Proguanil Hydrochloride works, or Atovaquone/Proguanil Hydrochloride itself can strengthen or weaken the effectiveness of other medicines taken at the same time. These include:

- **metoclopramide**, used to treat nausea and vomiting
- the antibiotics, **tetracycline**, **rifampicin** and **rifabutin**
- **efavirenz** or **certain highly active protease-inhibitors** used to treat HIV
- **warfarin** and other medicines that stop blood clotting
- **etoposide** used to treat cancer.

Tell your doctor if your child is taking any of these. Your doctor may decide that Atovaquone/Proguanil Hydrochloride isn't suitable for them, or that they need extra check ups whilst taking it.

Remember to tell your doctor if your child starts taking any other medicines while they're taking Atovaquone/Proguanil Hydrochloride.

Atovaquone/Proguanil Hydrochloride with food and drink

Give Atovaquone/Proguanil Hydrochloride with food or a milky drink, where possible. This will increase the amount of Atovaquone/Proguanil Hydrochloride your child's body can absorb, and make the treatment more effective.

Pregnancy, breast-feeding and fertility

If you or your child is pregnant, do not take Atovaquone/Proguanil Hydrochloride unless your doctor recommends it.

Do not breast feed while taking Atovaquone/Proguanil Hydrochloride, as the ingredients may pass into breast milk and may harm the baby.

Driving and using machines

If you feel dizzy, do not drive. Atovaquone/Proguanil Hydrochloride makes some people feel dizzy. If this happens to you, do not drive, use machines or take part in activities where you may put yourself or others at risk.

Atovaquone/Proguanil Hydrochloride contains sodium

This medicine contains less than 1 mmol sodium (23mg) per film-coated tablet, that is so to say essentially 'sodium-free'.

3. How to use Atovaquone/Proguanil Hydrochloride

Always give this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

Give Atovaquone/Proguanil Hydrochloride with food or a milky drink, where possible. The tablets should be swallowed whole. However, for children who find them difficult to swallow, they may be crushed just before being taken and mixed with food or a milky drink.

It is best to give Atovaquone/Proguanil Hydrochloride at the same time each day.

To prevent malaria:

The recommended dose to prevent malaria depends on your child's weight.

11-20 kg – 1 tablet once a day
21-30 kg – 2 tablets once a day (as a single dose)
31-40 kg – 3 tablets once a day (as a single dose)

- Start giving Atovaquone/Proguanil Hydrochloride 1 to 2 days before travelling to an area which has malaria.
- Continue giving it every day during the stay.
- Continue giving it for another 7 days after your return to a malaria-free area

For maximum protection your child must take the full course of treatment.

To treat malaria:

The recommended dose to treat malaria depends on your child's weight.

5-8 kg – 2 tablets once a day for 3 consecutive days
9-10 kg – 3 tablets once a day for 3 consecutive days

If your child is sick (*vomits*)

For preventing Malaria:

- if your child is sick (*vomits*) within 1 hour of taking Atovaquone/Proguanil Hydrochloride, give another dose straight away
- it is important to take the full course of Atovaquone/Proguanil Hydrochloride. If your child has to take extra tablets due to sickness, they may need another prescription.
- if your child has been vomiting, it is especially important to use extra protection, such as repellents and bednets. Atovaquone/Proguanil Hydrochloride may not be as effective, as the amount absorbed will be reduced.

For treating malaria:

- if your child has vomiting and diarrhea tell your doctor. Your child will need regular blood tests. Atovaquone/Proguanil Hydrochloride will not be as effective, as the amount absorbed will be reduced. The tests will check whether the malaria parasite is being cleared from their blood.

If your child takes more Atovaquone/Proguanil Hydrochloride than they should have

Contact a doctor or a pharmacist for advice. If possible show them the Atovaquone/Proguanil Hydrochloride pack.

If you forget to give Atovaquone/Proguanil Hydrochloride

It is very important that your child takes the full course of Atovaquone/Proguanil Hydrochloride. If you forget to give your child a dose, don't worry. Just give the next dose as soon as you remember. Then continue the treatment as before.

Don't take extra tablets to make up for a missed dose. Just take your next dose at the usual time.

Don't stop giving Atovaquone/Proguanil Hydrochloride without advice

Keep giving Atovaquone/Proguanil Hydrochloride for 7 days after you return to a malaria-free area. Give the full course of tablets for maximum protection. Stopping early puts your child at risk of getting malaria, as it takes 7 days to ensure that any parasites that may be in your blood following a bite from an infected mosquito are killed.

If you have any further questions on the use of this product, ask your doctor or pharmacist.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

Look out for the following severe reactions. They have occurred in a small number of people, but their exact frequency is unknown.

Severe allergic reactions - signs include:

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

Contact a doctor immediately if your child gets any of these symptoms. **Stop using Atovaquone/Proguanil Hydrochloride.**

Severe skin reactions

- 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*)
- severe 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.

Most of the other side effects reported have been mild and have not lasted very long:

Very common side effects (may affect more than 1 in 10 people)

- headache
- feeling sick and being sick (*nausea* and *vomiting*)
- stomach pains
- diarrhoea.

Common side effects (may affect up to 1 in 10 people):

- dizziness
- sleeping problems (*insomnia*)
- strange dreams
- depression
- loss of appetite
- fever
- rash which may be itchy
- cough.

Common side effects, which may show up in blood tests are:

- reduced numbers of red blood cells (*anaemia*) which can cause tiredness, headaches and shortness of breath

- reduced numbers of white blood cells (*neutropenia*) which may make you more likely to catch infections
- low levels of sodium in the blood (*hyponatraemia*)
- an increase in liver enzymes.

Uncommon side effects (may affect up to 1 in 100 people):

- anxiety
- an unusual awareness of abnormal beating of the heart (*palpitations*)
- swelling and redness of the mouth
- hair loss
- itchy, bumpy rash (hives).

Uncommon side effects that may show up in blood tests:

- an increase in amylase (*an enzyme produced in the pancreas*).

Rare side effects (may affect up to 1 in 1,000 people):

- seeing or hearing things that are not there (*hallucinations*)

Other side effects

Other side effects have occurred in a small number of people but their exact frequency is unknown.

- Inflammation of the liver (*hepatitis*)
- blockage of the bile ducts (*cholestatis*)
- increase in heart rate (*tachycardia*)
- inflammation of the blood vessels (*vasculitis*) which may be visible as red or purple raised spots on the skin but can affect other parts of the body
- fits (*seizures*)
- panic attacks, crying
- nightmares
- severe mental health problem in which the person loses contact with reality and is unable to think and judge clearly
- indigestion
- mouth ulcers
- blisters
- peeling skin
- increased sensitivity of the skin to sunlight.

Other side effects that may show up in blood tests:

- A decrease in all types of blood cells (*pancytopenia*).

Reporting of side effects

If your child gets any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme website www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store.

By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Atovaquone/Proguanil Hydrochloride

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the label and carton after EXP. The expiry date refers to the last day of that month.

Atovaquone/Proguanil Hydrochloride does not require any special storage conditions.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. This will help protect the environment.

6. Contents of the pack and other information

What Atovaquone/Proguanil Hydrochloride contains

The active ingredients are atovaquone and proguanil hydrochloride. Each tablet contains 62.5 mg of atovaquone and 25 mg of proguanil hydrochloride.

The other ingredients are:

Tablet core: Poloxamer 188, microcrystalline cellulose (E460), low-substituted hydroxypropyl cellulose (E463), sodium starch glycolate (Type A), silica colloidal anhydrous (E551), povidone (E2101), magnesium stearate (E572)

Tablet coating: hypromellose (E464), titanium dioxide (E171), macrogol (E1521), iron oxide red (E172).

Tell your doctor, before giving Atovaquone/Proguanil Hydrochloride to your child, if you think your child may be allergic to any of these ingredients.

What Atovaquone/Proguanil Hydrochloride looks like and contents of the pack

Atovaquone/Proguanil Hydrochloride film coated tablets are round, pink, biconvex film coated tablets debossed with 'I' on one side and '11' on the other side.

Atovaquone/Proguanil Hydrochloride is available in blister packs and HDPE containers

Pack sizes

Alu-Alu Blister: 1, 12, 21, 24, 28, 36 film-coated tablets

Alu-PVC Blister: 1, 12, 21, 24, 28, 36 film-coated tablets

HDPE containers: 30, 100 film-coated tablets

Not all pack sizes may be marketed.

Marketing Authorisation Holder

Amarox Limited

Congress House, 14 Lyon Road

Harrow, Middlesex HA1 2EN

United Kingdom

Manufacturer

Pharmadox Healthcare Ltd.

KW20A Kordin Industrial Park
Paola, PLA 3000
Malta

Amarox Limited
Congress House, 14 Lyon Road
Harrow, Middlesex HA1 2EN
United Kingdom

Amarox Pharma B.V.
Rouboslaan 32
2252 TR Voorschoten
Netherlands

This leaflet was last revised in 03/2023.