

Package leaflet: Information for the user
Atovaquone Glenmark 750 mg/5 ml oral suspension
(atovaquone)

Read all of this leaflet carefully before you start taking 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 you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor or pharmacist.
- This includes any possible side effects not listed in this leaflet. See section 4.

The name of your medicine is Atovaquone Glenmark 750 mg/5 ml oral suspension but will be referred to as Atovaquone throughout the remainder of the leaflet.

What is in this leaflet

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

1. What Atovaquone is and what it is used for

Atovaquone is used to treat a lung infection called Pneumocystis pneumonia (PCP) in people who cannot take the medicine co-trimoxazole.

This disease is caused by an organism called Pneumocystis jiroveci (which used to be called Pneumocystis carinii).

The active ingredient in Atovaquone is atovaquone. Atovaquone belongs to a group of anti-parasitic medicines known as antiprotozoals.

2. What you need to know before you take Atovaquone

Do not take Atovaquone:

- if you are allergic to atovaquone or any of the other ingredients of this medicine (listed in Section 6).

Warnings and precautions

Talk to your doctor or pharmacist before taking Atovaquone

Take special care with Atovaquone

Your doctor needs to know before you take Atovaquone:

- if you have kidney or liver disease.
- if you have diarrhoea, particularly when you start your treatment. Diarrhoea reduces the amount of Atovaquone your body absorbs, so the treatment may not be effective.
- if you are over 65 years of age.
- tell your doctor if any of these applies to you. Your doctor may decide that Atovaquone isn't suitable for you, or that you need extra check-ups while you're taking it.

Other medicines and Atovaquone

Tell your doctor or pharmacist if you're taking, have recently taken any other medicines, including any herbal medicines or other medicines you've bought without a prescription.

Some medicines can reduce the effectiveness of Atovaquone, or Atovaquone itself can change the effect of other medicines taken at the same time.

These include:

- the antibiotics rifampicin and rifabutin
- the antibiotic tetracycline

- metoclopramide used to treat nausea and vomiting
- indinavir, zidovudine or didanosine, used to treat HIV
- efavirenz or certain highly active protease inhibitors used to treat HIV
- etoposide used to treat cancer.

Tell your doctor if you are taking any of these. Your doctor may decide that Atovaquone isn't suitable for you, or that you need extra check-ups while you're taking it.

Remember to tell your doctor if you start taking any other medicine while you're taking Atovaquone.

Atovaquone with food and drink

Always take Atovaquone with food – preferably foods that are high in fat. This will increase the amount of Atovaquone that your body can absorb, and make your treatment more effective.

Ask your doctor for advice about which foods are suitable.

If you have difficulty in taking Atovaquone with food, talk to your doctor about alternative treatments.

Pregnancy, breast-feeding and fertility

- If you are pregnant, do not take Atovaquone unless your doctor recommends it. If you become pregnant while you are taking Atovaquone, ask your doctor for advice about whether you should continue the treatment. Ask your doctor or pharmacist for advice before taking this medicine while pregnant.
- Do not breast-feed while taking Atovaquone. It is not known whether Atovaquone passes into breast milk; if it does it may harm your baby.

Driving and using machines

Your ability to drive or use machinery is not expected to be affected while you're taking Atovaquone.

Atovaquone contains benzyl alcohol

This medicine contains 50.00 mg benzyl alcohol in each 5 ml.

Benzyl alcohol may cause allergic reactions.

Benzyl alcohol has been linked with the risk of severe side effects including breathing problems (called "gasping syndrome") in young children. Do not give to your newborn baby (up to 4 weeks old), unless recommended by your doctor.

Do not use for more than a week in young children (less than 3 years old), unless advised by your doctor or pharmacist.

Ask your doctor or pharmacist for advice if you are pregnant or breast-feeding or if you have a liver or kidney disease. This is because large amounts of benzyl alcohol can build-up in your body and may cause side effects (called "metabolic acidosis").

Atovaquone contains sodium

This medicine contains less than 1 mmol sodium (23 mg) in each 5 ml, that is to say essentially 'sodium free'.

3. How to take Atovaquone

Always take this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you're not sure.

Shake the bottle well before use.

Do not dilute Atovaquone.

Always take Atovaquone with food – preferably foods which are high in fat. This will greatly increase the amount of Atovaquone absorbed, and will make your treatment more effective.

How much to take

The recommended adult dose of Atovaquone is one 5 ml spoonful (containing 750 mg atovaquone), twice a day for 21 days.

Take one dose in the morning and one in the evening.

If you take more Atovaquone than you should

Contact your doctor or pharmacist for advice. If possible, show them the Atovaquone pack.

If you forget to take Atovaquone

If you forget to take a dose of Atovaquone, take the next dose as soon as you remember (again with food), and then continue the treatment as before. **Do not take a double dose to make up for a forgotten dose.**

If you stop taking Atovaquone

Don't stop Atovaquone without advice.

Take Atovaquone for as long as your doctor recommends. Don't stop unless your doctor advises you to – even if you are feeling better. If you do not complete the full course of treatment, the infection may come back.

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

4. Possible side effects

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

Very common side effects

These may affect more than 1 in 10 people:

- feeling sick (nausea)
- rash
- itching skin

Common side effects

These may affect up to 1 in 10 people:

- diarrhoea
- being sick (vomiting)
- headache
- sleeping problems (insomnia)
- high temperature (fever)
- allergic reactions, occasionally severe. Signs of allergic reactions include:
 - sudden wheezing, tightness of the chest or throat, or difficulty breathing
 - swollen eyelids, face, lips, tongue or other part of the body.
 - hives (urticaria)

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

- low levels of sodium in the blood (hyponatraemia)
- increases in liver enzymes
- reduced number of red blood cells (anaemia), which can cause tiredness, headaches and shortness of breath
- reduced number of some types of white blood cells (neutropenia).

Uncommon side effects

These may affect up to 1 in 100 people:

- an increase in amylase, which may show up in a blood test (amylase is an enzyme produced in the pancreas).

Other side effects

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

- skin rash, which may blister, and looks like small targets (central dark spot surrounded by paler area and 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.

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme at www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in **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

Keep out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the packaging. The expiry date refers to the last day of that month. Once opened, use within 21 days.

This medicinal product does not require any special storage conditions. Do not refrigerate or freeze.

If your medicine shows any signs of discolouration or deterioration consult your pharmacist for advice. If damaged, please tell your doctor or pharmacist.

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help to protect the environment.

6. Contents of the pack and other information

What Atovaquone contains

- Each 5 ml spoonful of suspension contains 750 mg atovaquone (1 ml of suspension contains 150 mg atovaquone).
- The other ingredients are benzyl alcohol, xanthan gum, poloxamer 188, saccharin sodium, purified water, tutti frutti flavouring, citric acid monohydrate and trisodium citrate dihydrate.

What Atovaquone looks like and contents of the pack

Atovaquone is a yellow liquid. This medicine is contained in a 250 ml plastic bottle with a child-resistant cap.

A 5 ml measuring spoon is included in each pack.

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Ltd, Tel: 01204 471 269**