

## **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.

#### **What is in this leaflet**

1. What Atovaquone Glenmark 750mg/5ml oral suspension is and what it is used for
2. What you need to know before you take Atovaquone Glenmark 750mg/5ml oral suspension
3. How to take Atovaquone Glenmark 750mg/5ml oral suspension
4. Possible side effects
5. How to store Atovaquone Glenmark 750mg/5ml oral suspension
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#### **1. What Atovaquone Glenmark 750mg/5ml oral suspension is and what it is used for**

Atovaquone Glenmark 750mg/5ml oral suspension 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 Glenmark 750mg/5ml oral suspension is atovaquone. Atovaquone Glenmark 750mg/5ml oral suspension belongs to a group of anti-parasitic medicines known as antiprotozoals.

#### **2. What you need to know before you take Atovaquone Glenmark 750mg/5ml oral suspension**

##### **Do not take Atovaquone Glenmark 750mg/5ml oral suspension:**

- 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 Glenmark 750mg/5ml oral suspension

Take special care with Atovaquone Glenmark 750mg/5ml oral suspension

Your doctor needs to know before you take Atovaquone Glenmark 750mg/5ml oral suspension:

- if you have kidney or liver disease.
- if you have diarrhoea, particularly when you start your treatment. Diarrhoea reduces the amount of Atovaquone Glenmark 750mg/5ml oral suspension 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 Glenmark 750mg/5ml oral suspension isn't suitable for you, or that you need extra check-ups while you're taking it.

### **Other medicines and Atovaquone Glenmark 750mg/5ml oral suspension**

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 Glenmark 750mg/5ml oral suspension 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 Glenmark 750mg/5ml oral suspension.

### **Atovaquone Glenmark 750mg/5ml oral suspension with food and drink**

Always take Atovaquone Glenmark 750mg/5ml oral suspension with food - preferably foods that are high in fat. This will increase the amount of Atovaquone Glenmark 750mg/5ml oral suspension 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 Glenmark 750mg/5ml oral suspension with food, talk to your doctor about alternative treatments.

### **Pregnancy, breast-feeding and fertility**

- If you are pregnant, do not take Atovaquone Glenmark 750mg/5ml oral suspension unless your doctor recommends it. If you become pregnant while you are taking Atovaquone Glenmark 750mg/5ml oral suspension, 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 Glenmark 750mg/5ml oral suspension. It is not known whether Atovaquone Glenmark 750mg/5ml oral suspension 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 Glenmark 750mg/5ml oral suspension.

### **Atovaquone Glenmark 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 Glenmark 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 Glenmark 750mg/5ml oral suspension**

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 Glenmark 750mg/5ml oral suspension.

Always take Atovaquone Glenmark 750mg/5ml oral suspension with food - preferably foods which are high in fat. This will greatly increase the amount of Atovaquone Glenmark 750mg/5ml oral suspension absorbed, and will make your treatment more effective.

#### **How much to take**

The recommended adult dose of Atovaquone Glenmark 750mg/5ml oral suspension 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 Glenmark 750mg/5ml oral suspension than you should**

Contact your doctor or pharmacist for advice. If possible, show them the Atovaquone Glenmark 750mg/5ml oral suspension pack.

#### **If you forget to take Atovaquone Glenmark 750mg/5ml oral suspension**

If you forget to take a dose of Atovaquone Glenmark 750mg/5ml oral suspension, 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 Glenmark 750mg/5ml oral suspension**

**Don’t stop Atovaquone Glenmark 750mg/5ml oral suspension without advice.**

#### **Take Atovaquone Glenmark 750mg/5ml oral suspension 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 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 at: [www.mhra.gov.uk/yellowcard](http://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 Glenmark 750mg/5ml oral suspension**

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 of the bottle. Once opened use within 21 days.

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

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 Glenmark 750mg/5ml oral suspension contains**

- Each 5 ml spoonful of Atovaquone Glenmark 750mg/5ml oral suspension suspension contains 750 mg of the active ingredient atovaquone (1 ml of Atovaquone Glenmark 750mg/5ml oral 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, tri-sodium citrate dihydrate

### **What Atovaquone Glenmark 750mg/5ml oral suspension looks like and contents of the pack**

Atovaquone Glenmark 750mg/5ml oral suspension oral suspension is a yellow liquid. The medicine is contained in a plastic bottle with child -resistant cap, containing 226 ml oral suspension. A 5ml measuring spoon is included in each pack.

### **Marketing Authorisation Holder and Manufacturer**

#### **Marketing Authorisation Holder:**

Glenmark Pharmaceuticals Europe Limited  
Laxmi House, 2B Draycott Avenue  
Kenton, Middlesex  
HA3 0BU  
United Kingdom

#### **Manufacturer:**

Glenmark Pharmaceuticals Europe Limited  
Building 2, Croxley Green Business Park,  
Croxley Green, Hertfordshire, WD18 8YA  
United Kingdom

Glenmark Pharmaceuticals s.r.o.

Production site address:

Glenmark Pharmaceuticals s.r.o., Fibichova 143, 566 17 VysokeMyto, Czech Republic

Registered Address:

Glenmark Pharmaceuticals s.r.o. Hvězdova 1716/2b, 140 78 Praha 4, Czech Republic

### **This medicinal product is authorised in the Member States of the EEA under the following names:**

UK:	Atovaquone Glenmark 750 mg/5 ml oral suspension
NL:	Atovaquon Glenmark 750 mg/5 ml suspensie voor oraal gebruik
PT:	Atovaquona Kabi
DE:	Atovaquon Glenmark 750 mg/5 ml Suspension zum Einnehmen
DK:	Atovaquone Glenmark
ES:	Atovacuona Glenmark 750 mg/5 ml suspensión oral EFG
FI:	Atovaquone Glenmark

SE: Atovaquone Glenmark  
NO: Atovaquone Glenmark  
FR: Atovaquone Biogaran 750 mg/5ml, suspension buvable  
IT: Atovquone Glenmark

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