

Wellvone® 750 mg/5 ml oral suspension

(atovaquone)

3004
13.10.25[6]

PATIENT INFORMATION LEAFLET

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

This medicine has been prescribed for you only. Don't pass it on to others. It may harm them, even if their signs of illness are the same as yours. Keep this leaflet. You may need to read it again.

If you have any further questions, ask your doctor or pharmacist.

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.

Your medicine is available using the above name but will be referred to as Wellvone throughout this leaflet.

What is in this leaflet:

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

1. WHAT WELLVONE IS AND WHAT IT IS USED FOR

Wellvone 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 Wellvone is atovaquone. Wellvone belongs to a group of anti-parasitic medicines known as antiprotozoals.

2. WHAT YOU NEED TO KNOW BEFORE YOU TAKE WELLVONE

Don't take Wellvone

- **If you're allergic** to atovaquone or any of the other ingredients of this medicine (listed in Section 6).

→ **Talk to your doctor or pharmacist before taking Wellvone.**

Take special care with Wellvone

Your doctor needs to know before you take Wellvone:

- if you have **kidney or liver disease**.
- if you have **diarrhoea**, particularly when you start your treatment. Diarrhoea reduces the amount of Wellvone 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 Wellvone isn't suitable for you, or that you need extra check-ups while you're taking it.**

Pregnancy, breast-feeding and fertility

- **If you are pregnant, do not take Wellvone** unless your doctor recommends it. **If you become pregnant** while you are taking Wellvone, 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 Wellvone.** It is not known whether Wellvone passes into breast milk; if it does it may harm your baby.

Other medicines and Wellvone

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 Wellvone, or Wellvone 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 Wellvone 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 Wellvone.

Wellvone with food and drink

Always take Wellvone with food - preferably foods that are high in fat. This will increase the amount of Wellvone 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 Wellvone with food, talk to your doctor about alternative treatments.

Driving and using machines

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

Wellvone contains benzyl alcohol

This medicine contains 50.66 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").

Wellvone 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 WELLVONE

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 Wellvone.

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

How much to take

The recommended adult dose of Wellvone is one 5 ml spoonful (containing 750 mg atovaquone), twice a day for 21 days. Use the larger end (5 ml end) of the spoon to measure the required dose. Take one dose in the morning and one in the evening.

If you take more Wellvone than you should

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

If you forget to take Wellvone

If you forget to take a dose of Wellvone, take the next dose as soon as you remember (again with food), and then continue the treatment as before.

Don't take a double dose to make up for a missed dose.

Don't stop Wellvone without advice.

Take Wellvone 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 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 WELLVONE

- Keep this medicine out of the sight and reach of children.
- Do not use this medicine after the expiry date shown on the label of the bottle. Once opened use within 21 days.
- Do not store above 25°C. Do not freeze.
- If the medicines become discoloured or show any other signs of deterioration, consult your pharmacist who will tell you what to do.
- 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 Wellvone contains

Each 5 ml spoonful of Wellvone suspension contains 750 mg of the active ingredient atovaquone (1 ml of Wellvone contains 150 mg atovaquone).

The other ingredients are benzyl alcohol, xanthan gum, poloxamer 188, saccharin sodium, purified water, tutti frutti flavouring (sweet orange oil, concentrated orange oil, propylene glycol, benzyl alcohol, vanillin, acetic aldehyde, amyl acetate and ethyl butyrate) (see section 2).

If you think you might be allergic to any of these ingredients:

→ **Tell your doctor and don't take Wellvone.**

What Wellvone looks like and contents of the pack

Wellvone oral suspension is a yellow liquid. The medicine is contained in a 240 ml plastic bottle with child-resistant cap.

A 5 ml measuring spoon is included in each pack.

Manufacturer and product licence holder

Wellvone is manufactured by GlaxoSmithKline Trading Services Limited, 12 Riverwalk, Citywest Business Campus, Dublin 24, Ireland.

Procured from within the EU by product licence holder Star Pharmaceuticals Ltd., 5 Sandridge Close, Harrow, Middlesex, HA1 1XD.

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