Package leaflet: Information for the user

Wellvone 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.

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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

Do not take Wellvone

- if you are allergic to atovaquone or any of the other ingredients of this medicine (listed in section 6)
- if you have ever developed a severe skin rash or skin peeling, blistering and/or mouth sores after taking Wellvone or other medicine with atovaquone.

Warnings and precautions
Talk to your doctor or pharmacist before taking 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

This medicine can cause serious skin reactions. Stop using Wellvone and seek medical attention immediately if you notice any of the symptoms related to these serious skin reactions described in section 4.

Tell your doctor if any of these applies to you. Your doctor may decide that Wellvone is not suitable for you, or that you need extra check-ups while you are taking it.

Other medicines and Wellvone
Tell your doctor or pharmacist if you are taking, have recently taken any other medicines, including any herbal medicines or other medicines you have 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 is not suitable for you, or that you need extra check-ups while you are taking it.

Remember to tell your doctor if you start taking any other medicine while you are 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.

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.

Driving and using machines
Your ability to drive or use machinery is not expected to be affected while you are 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) per 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 are 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 5 mL spoon provided. Wash the spoon with clean water after taking every 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. **Do not take a double dose to make up for a missed dose.**

If you stop taking Wellvone
Do not stop Wellvone without advice.
Take Wellvone for as long as your doctor recommends. Do not 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.

Stop using Wellvone and seek medical attention immediately if you notice any of the following symptoms:

Not known (frequency cannot be estimated from the available data):
- reddish non-elevated, target-like or circular patches on the trunk, often with central blisters, skin peeling, ulcers of mouth, throat, nose, genitals and eyes. These serious skin rashes can be preceded by fever and flu-like symptoms (*Stevens-Johnson syndrome*).
- widespread rash, high body temperature and enlarged lymph nodes (*DRESS syndrome or drug hypersensitivity syndrome*)
- 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*)

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)

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 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 which is stated on the label of the bottle. Once opened use within 21 days.

Do not store above 25 °C and do not freeze.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures 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 (E1519), xanthan gum, poloxamer 188, saccharin sodium, purified water, tutti frutti flavouring (sweet orange oil, concentrated orange oil, propylene glycol (E1520), benzyl alcohol (E1519), vanillin, acetic aldehyde, amyl acetate and ethyl butyrate). See section 2 for further information about benzyl alcohol and sodium in Wellvone.

If you think you might be allergic to any of these ingredients:
Tell your doctor and do not take Wellvone.

What Wellvone looks like and contents of the pack
Wellvone oral suspension is a yellow liquid. The medicine is supplied in a 240 mL plastic bottle with child-resistant cap, containing 226 mL oral suspension. A measuring spoon (5 mL) is included in each pack.

Marketing Authorisation Holder and Manufacturer

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Other formats:
To listen to or request a copy of this leaflet in Braille, large print or audio, please call, free of charge:
0800 198 5000 (UK Only)
Please be ready to give the following information:
Product name Wellvone
Reference number 10949/0271
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