

WELLVONE ORAL LIQUID SUSPENSION

Atovaquone

Consumer Medicine Information

What is in this leaflet?

Please read this leaflet carefully before you start Wellvone Suspension.

This leaflet answers some common questions about Wellvone Suspension. It does not contain all of the available information.

It does not take the place of talking to your doctor or pharmacist.

All medicines have risks and benefits. Your doctor has weighed the risks of you taking Wellvone Suspension against the benefits this medicine is expected to have for you.

If you have any concerns about taking this medicine, ask your doctor or pharmacist.

Keep this leaflet with the medicine.

You may need to read it again.

What Wellvone Suspension is used for

Atovaquone the active ingredient in Wellvone Suspension belongs to a group of medicines called anti-infectives.

Wellvone Suspension is used to treat a type of pneumonia (lung infection) caused by *Pneumocystis carinii*.

Pneumocystis carinii is a parasite that can lie dormant in the airways unless the body's immune system becomes weakened, for example in human immunodeficiency virus

(HIV) infection. This can lead to *Pneumocystis carinii* pneumonia (PCP).

Wellvone Suspension works by interfering with important functions within *Pneumocystis carinii*.

Your doctor may have prescribed Wellvone Suspension for another reason.

Ask your doctor if you have any questions about why Wellvone Suspension has been prescribed for you.

This medicine is available only with a doctor's prescription. Wellvone Suspension is not addictive.

Before you take Wellvone Suspension

When you must not take it

- **Do not take Wellvone Suspension if you have ever had an allergic reaction to atovaquone or any of the ingredients listed at the end of this leaflet.** Symptoms of an allergic reaction may be mild or severe. They usually include some or all of the following: wheezing, swelling of the lips/mouth, difficulty in breathing, hayfever, lumpy rash ("hives") or fainting.
- **Do not take Wellvone Suspension if you are pregnant, trying to become pregnant or breastfeeding, unless your doctor says you should.**

Your doctor will discuss the risks and benefits of using Wellvone Suspension if you are pregnant or breastfeeding.

- **Do not take Wellvone Suspension after the expiry date (EXP) printed on the pack.** If you take it after the expiry date has passed, it may not work as well.
- **Do not take Wellvone Suspension if the packaging is torn or shows signs of tampering.** If you're not sure whether you should be taking Wellvone Suspension, talk to your doctor.

Before you start to take it

You must tell your doctor if:

- you are allergic to foods, dyes, preservatives or any other medicines.
- you have or have had diarrhoea or any other stomach or bowel problem.
- you have or have had kidney or liver disease.
- you have taken or are taking any medicine containing rifampicin (for example, Rifadin), rifabutin (for example Mycobutin), tetracycline (for example, Achromycin), zidovudine (for example, Retrovir) or metoclopramide (for example, Maxolon), indinavir (for example Crixivan).

Taking other medicines

Tell your doctor if you are taking any other medicines, including medicines you buy without a prescription from a pharmacy, supermarket or health food shop.

Make sure you tell your doctor if you have taken or are taking any medicine containing rifampicin, rifabutin, tetracycline, zidovudine, indinavir or metoclopramide. Example of branded medicines containing these active ingredients are given under the “Before you start to take it” section above.

Some medicines may affect the way others work. Your doctor or pharmacist will be able to tell you what to do when taking Wellvone Suspension with other medicines.

Use in children

There is insufficient information to recommend that children can take Wellvone Suspension.

How to take Wellvone Suspension

The Pharmacist's label on the pack will tell you how to take Wellvone Suspension. If there is something you do not understand, ask your doctor or pharmacist.

How much to take

The usual dose in adults is one 5 mL spoonful (750 mg), taken twice a day with food, for 21 days.

It is important to take the recommended dose (5 mL: 750 mg) twice a day because this dosing schedule provides the optimum drug concentration in your blood. However, if you have difficulty with swallowing or are only able to eat one meal a day, then the dose is two 5 mL spoonfuls (1500 mg) taken with a meal, for 21 days.

How to take it

It is very important that you take Wellvone Suspension with food. It has been shown that taking Wellvone Suspension with a high fat meal helps your medicine to work more effectively.

Make sure you shake the bottle of Wellvone Suspension before measuring your dose.

Wellvone Suspension should not be diluted.

When to take it

It is very important that you take Wellvone Suspension with food.

How long to take it

The usual course of treatment with Wellvone Suspension is 21 days.

If you forget to take it

If it is almost time for your next dose, skip the dose you missed and take your next dose when you are meant to. Otherwise, take it as soon as you remember, then go back to taking it as you would normally.

Do not take a double dose to make up for the dose that you missed.

If you take too much (overdose)

Immediately telephone your doctor or Poisons Information Centre (telephone 131126) for advice, if you think you or anyone else may have taken too much Wellvone Suspension, even if there are no signs of discomfort or poisoning. You may need urgent medical attention.

Keep telephone numbers for these places handy.

If you are not sure what to do, contact your doctor or pharmacist.

While you are taking Wellvone Suspension

Things you must do

Tell your doctor or pharmacist that you are taking Wellvone Suspension if you are about to be started on any new medicines.

Tell your doctor if you become pregnant or are trying to become pregnant.

Tell your doctor if, for any reason, you have not taken your medicine exactly as prescribed. Otherwise, your doctor may think that it was not effective and change your treatment unnecessarily.

Things you must not do

Do not stop taking Wellvone Suspension, or change the dose without first checking with your doctor.

Do not give this medicine to anyone else, even if their symptoms seem similar to yours.

Do not use Wellvone Suspension to treat any other complaints unless your doctor says to.

Things to be careful of

Be careful driving or operating machinery until you know how Wellvone Suspension affects you. Wellvone Suspension generally does not cause any problems with your ability to drive a car or operate machinery. However, as with many other medicines, Wellvone Suspension may cause headache in some people.

Side-Effects

Check with your doctor as soon as possible if you have any problems while taking Wellvone Suspension, even if you do not think the problems are connected with the medicine or are not listed in this leaflet.

In clinical studies, Wellvone Suspension has been used to treat

pneumocystis carinii pneumonia in patients with underlying HIV infection. Therefore it is not known whether many of these side-effects are due to taking Wellvone Suspension or taking Wellvone Suspension with other medicines. Some of these symptoms may occur as part of advanced HIV disease.

Like other medicines, Wellvone Suspension can cause some side-effects. If they occur, they are most likely to be minor and temporary. However, some may be serious and need medical attention.

The most commonly reported side-effects are:

- rash
- nausea, vomiting
- diarrhoea
- headache
- fever
- difficulty in sleeping

Ask your doctor or pharmacist to answer any questions you may have.

Tell your doctor or pharmacist immediately if you notice any of the following:

- weakness
- itchiness
- oral thrush
- abdominal pain
- constipation
- dizziness
- cough
- anxiety
- anorexia
- difficulty swallowing
- taste disturbance
- hay fever
- sinusitis
- abnormal blood sugar
- low blood pressure
- insomnia

A small number of patients have had other unwanted effects after taking Wellvone. These include unwanted effects on the liver and blood.

Ask your doctor or pharmacist to answer any questions you may have.

If you think you are having an allergic reaction to Wellvone Suspension, TELL YOUR DOCTOR IMMEDIATELY or go to the casualty department at your nearest hospital. Symptoms usually include some or all of the following:

- wheezing
- swelling of the lips/mouth
- difficulty in breathing
- hay fever
- lumpy rash ("hives")
- fainting

This is not a complete list of all possible side-effects. Others may occur in some people and there may be some side-effects not yet known.

Tell your doctor if you notice anything else that is making you feel unwell, even if it is not on this list.

Ask your doctor or pharmacist if you don't understand anything in this list.

Do not be alarmed by this list of possible side-effects. You may not experience any of them.

After taking Wellvone Suspension

Storage

Keep this medicine where young children cannot reach it.

A locked cupboard at least one-and-a-half metres above the ground is a good place to store medicines.

Keep Wellvone Suspension in a cool, dry place where it stays below 25°C.

Wellvone Suspension should not be frozen.

Do not store it, or any other medicine, in a bathroom or near a sink.

Do not leave it in the car or on window sills.

Heat and dampness can destroy some medicines.

Keep your Wellvone Suspension in its pack until it is time to take it.

If you take the Wellvone Suspension out of its pack it may not keep well.

Disposal

If your doctor tells you to stop taking Wellvone Suspension, or the Product has passed its expiry date, ask your pharmacist what to do with any Wellvone Suspension left over.

Product description

What Wellvone Suspension looks like.

Wellvone Suspension is a bright yellow liquid with a sweet, fruity odour. The plastic bottle contains 210 mL of suspension and is packed in a box with a plastic spoon.

Ingredients

Active ingredient:

Wellvone Suspension contains the active ingredient atovaquone.

Inactive ingredients:

Wellvone Suspension also contains benzyl alcohol, xanthan gum, poloxamer 188, saccharin sodium, Tutti Frutti flavour 51880 A (PI 965) and purified water.

Wellvone Suspension does not contain gluten or lactose.

Sponsor

Aspen Pharmacare Australia Pty Ltd
34-36 Chandos Street
St Leonards NSW 2065
Australia.

Further Information

Pharmaceutical companies are not in a position to give people an individual diagnosis or medical advice. Your doctor or pharmacist is the best person to give you advice on the treatment of your condition. You may also be able to find general information about your disease and its treatment from books, for example in public libraries.

Do not throw this leaflet away.

You may need to read it again.

The information provided applies only to: Wellvone Suspension.

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