

Consumer Medicine Information (CMI) summary

The [full CMI](#) on the next page has more details. If you are worried about using this medicine, speak to your doctor or pharmacist.

1. Why am I using ATOVACUE?

ATOVACUE contains the active ingredient atovaquone. ATOVACUE is used to treat a type of pneumonia (lung infection) caused by *Pneumocystis carinii*.

For more information, see Section [1. Why am I using ATOVACUE?](#) in the full CMI.

2. What should I know before I use ATOVACUE?

Do not use if you have ever had an allergic reaction to atovaquone or any of the ingredients listed at the end of the CMI.

Talk to your doctor if you have any other medical conditions, take any other medicines, or are pregnant or plan to become pregnant or are breastfeeding.

For more information, see Section [2. What should I know before I use ATOVACUE?](#) in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with ATOVACUE and affect how it works.

A list of these medicines is in Section [3. What if I am taking other medicines?](#) in the full CMI.

4. How do I use ATOVACUE?

- It is very important that you take ATOVACUE oral suspension with food. It has been shown that taking ATOVACUE Suspension with a high fat meal helps your medicine to work more effectively.
- Shake well before use. Do not dilute.

More instructions can be found in Section [4. How do I use ATOVACUE?](#) in the full CMI.

5. What should I know while using ATOVACUE?

Things you should do	<ul style="list-style-type: none">• Remind any doctor, dentist or pharmacist you visit that you are using ATOVACUE.• Tell your doctor or pharmacist that you are taking ATOVACUE 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.
Things you should not do	<ul style="list-style-type: none">• Do not stop using this medicine suddenly.• Do not give this medicine to anyone else, even if their symptoms seem similar to yours.• Do not use ATOVACUE to treat any other complaints unless your doctor says to.
Driving or using machines	<ul style="list-style-type: none">• Be careful driving or operating machinery until you know how ATOVACUE affects you.
Drinking alcohol	<ul style="list-style-type: none">• Tell your doctor if you drink alcohol.
Looking after your medicine	<ul style="list-style-type: none">• Store below 25°C. Do not refrigerate. Do not freeze.

For more information, see Section [5. What should I know while using ATOVACUE?](#) in the full CMI.

6. Are there any side effects?

Common side effects include fever, headache, abdominal pain, asthenia, nausea, diarrhoea, vomiting, dyspepsia, insomnia, rash and sinusitis.

For more information, including what to do if you have any side effects, see Section [6. Are there any side effects?](#) in the full CMI.

ATOVACUE®

Active ingredient: Atovaquone

Consumer Medicine Information (CMI)

This leaflet provides important information about using ATOVACUE. **You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about using ATOVACUE.**

Where to find information in this leaflet:

- [1. Why am I using ATOVACUE?](#)
- [2. What should I know before I use ATOVACUE?](#)
- [3. What if I am taking other medicines?](#)
- [4. How do I use ATOVACUE?](#)
- [5. What should I know while using ATOVACUE?](#)
- [6. Are there any side effects?](#)
- [7. Product details](#)

1. Why am I using ATOVACUE?

ATOVACUE contains the active ingredient atovaquone. ATOVACUE belongs to a group of medicines called anti-infectives.

ATOVACUE oral 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).

ATOVACUE suspension works by interfering with important functions within *Pneumocystis carinii*.

Your doctor may have prescribed ATOVACUE suspension for another reason.

Ask your doctor if you have any questions about why ATOVACUE suspension has been prescribed for you.

This medicine is available only with a doctor's prescription. ATOVACUE suspension is not addictive.

2. What should I know before I use ATOVACUE?

Warnings

Do not use ATOVACUE if:

- you are allergic to atovaquone, or any of the ingredients listed at the end of this leaflet.
- Always check the ingredients to make sure you can use this medicine.
- you are pregnant, trying to become pregnant or breastfeeding, unless your doctor says you should.

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

Benzyl alcohol may cause allergic reactions.

Check with your doctor if you:

- are allergic to foods, dyes, preservatives or any other medicines.
- have or have had diarrhoea or any other stomach or bowel problem.
- have or have had kidney or liver disease.

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them. See additional information under Section [6. Are there any side effects?](#)

Pregnancy and breastfeeding

Check with your doctor if you are pregnant or intend to become pregnant.

Talk to your doctor if you are breastfeeding or intend to breastfeed.

3. What if I am taking other medicines?

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

Some medicines may interfere with ATOVACUE and affect how it works.

Medicines that may increase the effect of ATOVACUE include:

- Indinavir, medicines used to treat HIV/ AIDS.
- Warfarin, a medicine used to prevent blood clots.

Medicines that may reduce the effect of ATOVACUE include:

- Metoclopramide, a medicine used for nausea and vomiting.
- Rifampicin (for example Rifadin)
- tetracycline (for example Doxylin)
- rifabutin (for example Mycobutin)
- cephalosporins (for example cefuroxime)
- medicines used to treat bacterial infections.
- anti-diarrhoeals and laxatives
- Paracetamol
- Benzodiazepines, medicines used to treat anxiety, seizures and insomnia.
- Aciclovir, a medicine used to treat viral infections.
- Opiates,(for example morphine, codeine and oxycodone).

Drugs that get affected by Atovacue Suspension:
Zidovudine

Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect ATOVACUE.

4. How do I use ATOVACUE ?

How much to take / use

Dosage in adults

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.

When to take / use ATOVACUE

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

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

ATOVACUE Suspension should not be diluted.

If you forget to use ATOVACUE

ATOVACUE should be used regularly at the same time each day. If you miss your dose at the usual time, take it as soon as you remember.

If it is almost time for your next dose, skip the dose you missed and take your next dose when you are meant to.

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

If you use too much ATOVACUE

If you think that you have used too much ATOVACUE, you may need urgent medical attention.

You should immediately:

- phone the Poisons Information Centre (by calling 13 11 26), or
- contact your doctor, or
- go to the Emergency Department at your nearest hospital.

You should do this even if there are no signs of discomfort or poisoning.

5. What should I know while using ATOVACUE?

Things you should do

Tell your doctor or pharmacist that you are taking ATOVACUE 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 should not do

- Do not stop taking ATOVACUE 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 ATOVACUE suspension to treat any other complaints unless your doctor says to.

Driving or using machines

Be careful before you drive or use any machines or tools until you know how ATOVACUE suspension affects you.

ATOVACUE suspension generally does not cause any problems with your ability to drive a car or operate machinery. However, as with many other medicines, ATOVACUE suspension may cause headache in some people.

Drinking alcohol

Tell your doctor if you drink alcohol.

Looking after your medicine

Follow the instructions in the carton on how to take care of your medicine properly.

Store below 25°C. Do not refrigerate. Do not freeze.

Unused product should be discarded 21 days after opening.

Do not store it:

- in the bathroom or near a sink, or
- in the car or on window sills.

Keep it where young children cannot reach it.

When to discard your medicine

If your doctor tells you to stop taking it or the suspension have passed their expiry date, ask your pharmacist what to do with any that are left over.

Getting rid of any unwanted medicine

If you no longer need to use this medicine or it is out of date, take it to any pharmacy for safe disposal.

Do not use this medicine after the expiry date.

6. Are there any side effects?

All medicines can have side effects. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention.

See the information below and, if you need to, ask your doctor or pharmacist if you have any further questions about side effects.

In clinical studies, atovaquone 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 atovaquone suspension or taking atovaquone suspension with other medicines. Some of these symptoms may occur as part of advanced HIV disease.

Like other medicines, ATOVACUE 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.

Less serious side effects

Less serious side effects	What to do
<p>Body as a whole:</p> <ul style="list-style-type: none"> • Fever • Weakness • Anorexia • nausea, vomiting <p>Gastrointestinal System:</p> <ul style="list-style-type: none"> • Oral thrush • Indigestion • abdominal pain • constipation • difficulty swallowing • taste disturbance • diarrhoea <p>Central Nervous System:</p> <ul style="list-style-type: none"> • anxiety • dizziness • insomnia / difficulty in sleeping • headache <p>Cardiovascular System:</p> <ul style="list-style-type: none"> • low blood pressure • abnormal blood sugar <p>Respiratory System:</p> <ul style="list-style-type: none"> • Sinusitis • Cough • Rhinitis <p>Skin and Appendages:</p> <ul style="list-style-type: none"> • Itchiness • rash 	<p>Speak to your doctor if you have any of these less serious side effects and they worry you.</p>

Serious side effects

Serious side effects	What to do
<p>Symptoms of allergic reaction:</p> <ul style="list-style-type: none"> • wheezing • swelling of the lips/mouth • difficulty in breathing • hay fever • lumpy rash ("hives") • fainting 	<p>Call your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you notice any of these serious side effects.</p>

Tell your doctor or pharmacist if you notice anything else that may be making you feel unwell.

Other side effects not listed here may occur in some people.

Reporting side effects

After you have received medical advice for any side effects you experience, you can report side effects to the Therapeutic Goods Administration online at www.tga.gov.au/reporting-problems. By reporting side effects, you can help provide more information on the safety of this medicine.

Always make sure you speak to your doctor or pharmacist before you decide to stop taking any of your medicines.

7. Product details

This medicine is only available with a doctor's prescription.

What ATOVACUE contains

Active ingredient	Atovaquone
Other ingredients	Benzyl alcohol Xanthan Gum Poloxamer 188 Hypromellose Saccharin sodium Citric acid monohydrate Sodium citrate dihydrate Purified water Tutti Frutti Flavour (051880AP0551)

Do not take this medicine if you are allergic to any of these ingredients.

What ATOVACUE looks like

ATOVACUE is 210 mL bright yellow flavoured suspension filled in 250 mL plastic bottle (HPDE) with 28 mm child resistance (CR) clean peel closure and polypropylene double sided spoon (2.5 ml and 5 ml). (AUST R 407150).

Who distributes ATOVACUE

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