

Zidoval®

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 Zidoval?

Zidoval contains the active ingredient metronidazole. Zidoval is used to treat vaginal infections (bacterial vaginosis) caused by certain bacteria.

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

2. What should I know before I use Zidoval?

Do not use if you have ever had an allergic reaction to metronidazole 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 Zidoval?](#) in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with Zidoval 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 Zidoval?

- Use one applicator filled with Zidoval gel. Apply at bedtime
- Follow the instructions provided in the package insert on how to apply your dose of Zidoval.

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

5. What should I know while using Zidoval?

Things you should do	
	<ul style="list-style-type: none">• Remind any doctor, dentist or pharmacist you visit that you are using Zidoval.• Tell your doctor immediately if you

	<p>become pregnant whilst using Zidoval.</p> <ul style="list-style-type: none"> ● If you are about to have a blood test, tell your doctor you are using Zidoval. ● Avoid sexual intercourse while you have a vaginal infection and when using Zidoval. ● After completing a course of Zidoval, see your doctor to confirm that the infection has cleared up.
Things you should not do	<ul style="list-style-type: none"> ● Zidoval is for vaginal use only. Do not use it any other way.
Driving or using machines	<ul style="list-style-type: none"> ● Whilst Zidoval is not expected to affect your ability to drive or operate machinery, be careful with these activities until you know how Zidoval how affects you.
Drinking alcohol	<ul style="list-style-type: none"> ● Discuss with your doctor whether you may drink alcohol during treatment with Zidoval.

	<ul style="list-style-type: none">• Drinking alcohol when using Zidoval may make you feel dizzy or sick.
Looking after your medicine	<ul style="list-style-type: none">• Store Zidoval in a cool dry place below 25°C.

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

6. Are there any side effects?

Common side effects include nausea and vomiting, upset stomach or pain, vaginal discharge, vaginal or vulval irritation, yeast infection, pelvic discomfort, unpleasant taste or feeling on the tongue, decreased appetite, dizziness, headache. Serious side effects include allergic reaction, darkened urine, yellowing of the skin or eyes and seizures.

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.

Zidoval®

Active ingredient: *Metronidazole*

Consumer Medicine Information (CMI)

This leaflet provides important information about using Zidoval. **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 Zidoval.**

Where to find information in this leaflet:

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

1. Why am I using Zidoval?

Zidoval contains the active ingredient metronidazole. Zidoval is an antibacterial agent used to kill certain bacteria.

Zidoval is used to treat vaginal infections (bacterial vaginosis) caused by certain bacteria.

It is not suitable for all types of vaginal infections. By applying Zidoval directly into the vagina, it can kill the bacteria at the site of the infection.

2. What should I know before I use Zidoval?

Warnings

Do not use Zidoval if:

- you are allergic to metronidazole, other nitroimidazole derivatives or any of the ingredients listed at the end of this leaflet.
- Always check the ingredients to make sure you can use this medicine
- the packaging is torn or shows signs of tampering.

Check with your doctor if you:

- have any allergies to any other medicines, foods, preservatives or dyes
- have any other medical conditions including a disease of the blood, liver, kidneys, or central nervous system
- have a condition called Cockayne syndrome, also called Neill-Dingwall syndrome
- have, or think you have vaginal thrush (candidiasis). The symptoms of vaginal thrush may become more noticeable when you use Zidoval, and you may need another treatment from your doctor for this.

- take any medicines for any other condition
- are having your period or are about to start your period. Your doctor may wait until your period is finished before commencing treatment.
- have taken disulfiram (Antabuse) in the past 2 weeks. Disulfiram is used to help people who have a drinking problem. If disulfiram and Zidoval are taken closely together, serious unwanted effects may occur.

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

Talk with your doctor if you are pregnant or breastfeeding.

Metronidazole crosses the placenta and may harm your unborn baby.

Your doctor can discuss with you benefits and risks of taking Zidoval while you are pregnant or breastfeeding.

Use in Children

Do not give Zidoval to a child under 12 years of age. Safety and effectiveness of Zidoval have not been established in this age group.

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 Zidoval and affect how it works including:

- medicines to prevent blood clotting (e.g., warfarin)
- lithium
- cyclosporin
- 5-fluorouracil
- carmustine (BCNU) or cyclophosphamide
- disulfiram.

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

4. How do I use Zidoval?

How much to use

- Each dose consists of one applicator filled with 5 g of Zidoval gel.
- Apply Zidoval for 5 days in a row or for as long as your doctor tells you.

To help prevent reinfection, always complete the full course even if your symptoms start to clear up within a few days.

When to use Zidoval

- Use Zidoval at bedtime

Vaginal medicines can leak out of the vagina during treatment. Using Zidoval at bedtime will help reduce leakage.

Wear a panty liner or sanitary napkin during treatment to help keep Zidoval from getting onto your clothes. Do not use tampons as they may soak up the medicine and stop you receiving the full dose.

How to apply Zidoval

Your box of Zidoval contains a tube of vaginal gel and five single use vaginal applicators.

To ensure maximum hygiene always:

- wash your hands before opening the tube or touching the applicator
- use a new applicator for each dose
- dispose of the used applicator in the rubbish bin.

Opening the tube

Before using Zidoval for the first time, puncture the metal seal on the tube. To do this, unscrew the cap from the tube and pierce the seal using the pointed tip of the cap.

Filling the applicator

Step 1:

Remove an applicator from its wrapper. Unscrew the cap from the tube and screw the open end of the applicator onto the tube.

Step 2:

Squeeze the tube slowly from the bottom to fill the applicator with gel. The plunger will move as the applicator fills and will stop moving when the applicator contains the correct amount of gel.

Step 3:

Unscrew the applicator and replace the cap on the tube.

Inserting the applicator

Hold the filled applicator by its barrel and gently insert it into your vagina as far as it will comfortably go.

You may find it easiest to do whilst lying on your back with your knees bent. Otherwise choose any position you find comfortable.

Applying the gel

Slowly press the plunger to deposit the gel into your vagina. Continue pressing until the plunger stops. This will ensure you have released the correct amount of gel. Remove the applicator from the vagina and put it in the rubbish bin.

If you forget to use Zidoval

Zidoval should be used regularly at the same time each day. If you miss your dose at the usual time, use it as soon as you remember and continue with your treatment as before.

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 Zidoval

If you think that you have used too much Zidoval, 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 Zidoval?

Things you should do

Call your doctor straight away if you:

- become pregnant while using this medicine.

Remind any doctor, dentist, or pharmacist you visit that you are using Zidoval.

If you going to have surgery, tell the surgeon or anaesthetist that you are using Zidoval.

If you are about to have a blood test, tell you doctor that you are using Zidoval. It may interfere with the results of some tests.

Avoid sexual intercourse during the infection and whilst you are using Zidoval.

Zidoval contains ingredients that may cause burning or irritation of the eye. If you accidentally get Zidoval in your eye, rinse the eye immediately with plenty of cool tap water.

After you have finished your course of Zidoval, see your doctor to check your progress. This is to ensure that the infection has cleared up.

Things you should not do

- Zidoval is for vaginal use only. Do not use it in any other way.

- Do not give your medicine to anyone else, even if they have the same condition as you.
- Do not stop using Zidoval or change the dose without checking with your doctor.

Driving or using machines

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

Whilst Zidoval is not expected to affect your ability to drive or use machinery, caution is appropriate.

Tell your doctor if you drink alcohol.

Drinking alcohol during treatment with Zidoval may make you feel dizzy or sick.

Looking after your medicine

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

Store Zidoval below 25°C in a cool dry place away from moisture, heat, or sunlight; for example, 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.

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.

Less serious side effects

Less serious side effects	What to do
<ul style="list-style-type: none">• nausea and vomiting• decreased appetite• stomach upset or pain• diarrhoea• vaginal discharge• vaginal or vulval irritation• yeast infection• pelvic discomfort• unpleasant taste or feeling on the tongue• skin itch or rash• dizziness• headache.	<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
<ul style="list-style-type: none">• allergic reaction• darkened urine• yellowing of the skin or eyes• seizures.	Call your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you notice this serious side effect.

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 Zidoval contains

Active ingredient (main ingredient)	Metronidazole
Other ingredients (inactive ingredients)	Carbomer 974P Propylene glycol Methyl hydroxybenzoate Propyl hydroxybenzoate Disodium edetate Sodium hydroxide Purified water
Potential allergens	Methyl hydroxybenzoate Propyl hydroxybenzoate

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

What Zidoval looks like

Zidoval is a colourless to straw-coloured gel contained in an aluminium tube. Each 5 g of Zidoval vaginal gel (one full applicator) contains 37.5 mg of metronidazole as the active ingredient.

Registration number: AUST R 73743.

Who distributes Zidoval

iNova Pharmaceuticals (Australia) Pty Limited

ABN: 13 617 871 539

Level 10, 12 Help Street

Chatswood NSW 2067

Tel: 1800 630 056

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