

Zidoval® Vaginal Gel

Metronidazole 0.75% w/w

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about Zidoval Vaginal Gel. It does not contain all 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 Zidoval against the benefits they expect it will 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 Zidoval is used for

Zidoval Vaginal Gel contains an active ingredient, metronidazole. Metronidazole is an antibacterial agent.

Zidoval is used to treat infection of the vagina (bacterial vaginosis) caused by certain bacteria. It is not suitable for all types of vaginal infections. By applying Zidoval directly into the vagina, metronidazole can kill the bacteria at the site of the infection.

Ask your doctor if you have any questions about why this medicine has been prescribed for you.

Your doctor may have prescribed it for another reason.

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

Before you use Zidoval

When you must not use it

Do not use Zidoval if you have an allergy to:

- any medicine containing metronidazole
- any of the ingredients listed at the end of this leaflet.

Some of the symptoms of an allergic reaction may include:

- shortness of breath
- wheezing or difficulty breathing
- swelling of the face, lips, tongue or other parts of the body
- rash, itching or hives on the skin.

Do not give Zidoval to a child under the age of 12 years.

Safety and effectiveness in children younger than 12 years have not been established.

Do not use this medicine after the expiry date printed on the pack or if the packaging is torn or shows signs of tampering.

If it has expired or is damaged, return it to your pharmacist for disposal.

If you are not sure whether you should start using this medicine, talk to your doctor.

Before you start to use it

Tell your doctor if you have allergies to any other medicines, foods, preservatives or dyes.

Tell your doctor if you have or have had any of the following medical conditions:

- a disease of the blood, liver, kidneys or central nervous system
- Cockayne syndrome, also called Neill-Dingwall syndrome.

Tell your doctor if you are pregnant or breast-feeding.

Your doctor can discuss with you the risks and benefits of using Zidoval whilst pregnant or breastfeeding.

Tell your doctor if you have, or think you may have vaginal thrush (candidiasis).

The symptoms of vaginal thrush may become more noticeable when you use Zidoval gel and you may need another treatment from your doctor for this.

Tell your doctor if:

- you are having your period or are about to start your period
- you have taken disulfiram (Antabuse) in the past 2 weeks.

Disulfiram is used to help people who have a drinking problem. If Zidoval and disulfiram are taken close together, serious unwanted effects may occur.

If you have not told your doctor about any of the above, tell them before you start using Zidoval.

Taking other medicines

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

Some medicines and Zidoval may interfere with each other. These include:

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

These medicines may be affected by Zidoval or may affect how well it works. You may need different amounts of your medicines, or you may need to take different medicines.

Your doctor and pharmacist have more information on medicines to be careful with or avoid while using this medicine.

Discuss with your doctor whether you may drink alcohol during treatment with Zidoval.

Drinking alcohol when using Zidoval may make you feel dizzy or sick.

How to use Zidoval

Follow all directions given to you by your doctor or pharmacist carefully.

They may differ from the information contained in this leaflet.

If you do not understand the instructions in this leaflet, ask your doctor or pharmacist for help.

How much to use

Each dose consists of one applicator filled with 5 g of Zidoval gel.

How to use it

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 Vaginal Gel 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 this 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.

When to use it

Use Zidoval at bedtime.

Vaginal medicines can leak out of the vagina during treatment. Using Zidoval at bedtime will help reduce leakage. Using Zidoval at the same time each day will also help you remember when to use it.

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

How long to use it

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 of treatment even if your symptoms start to clear up within a few days.

If you forget to use it

If you forget to have a dose of Zidoval gel, use it as soon as you remember and continue with your treatment as before.

If, by the time you remember, it is time to have your next dose, do not double-up on your treatment. Have your original missed dose and continue your treatment as usual. Never have more than one dose of the gel a day to make up for missed doses.

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

If you have trouble remembering to use your medicine, ask your pharmacist for some hints.

If you use too much (overdose)

Telephone your doctor or the Poisons Information Centre (telephone 13 11 26) for advice, or go to Accident and Emergency at the nearest hospital, if you think that you or anyone else may have accidentally swallowed Zidoval Vaginal Gel or may have used too much of it. Do this even if there are no signs of discomfort or poisoning.

You may need medical attention.

While you are using Zidoval

Things you must do

If you are about to be started on any new medicine remind your doctor and pharmacist that you are using Zidoval.

Tell any other doctors and pharmacists who treat you that you are using this medicine.

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

It may affect other medicines used during surgery.

As with all vaginal infections avoid sexual intercourse during the infection and whilst you are using Zidoval gel.

If you become pregnant while using this medicine, tell your doctor immediately.

If you are about to have any blood tests tell your doctor that you are using this medicine.

It may interfere with the results of some tests.

Keep all of your doctor's appointments so that your progress can be checked.

It is important that your doctor check your progress after you finish using Zidoval. This is to make sure that the infection has cleared up.

Things you must not do

Do not use Zidoval to treat any other complaints unless your doctor tells you to.

Do not give your medicine to anyone else, even if they have the same condition as you.

Do not stop using your medicine or change the dose without checking with your doctor.

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

Things to be careful of

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

Side effects

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are using Zidoval.

All medicines can have side effects. Sometimes they are serious, most of the time they are not. You may need medical attention if you get some of the side effects.

Do not be alarmed by the following list of side effects. You may not experience any of them.

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

Tell your doctor or pharmacist if you notice any of the following and they worry you:

- abnormal vaginal discharge
- itching, burning or swelling in or around the vagina
- a feeling of increased pressure in the pelvic area
- stomach cramp or pain
- feeling sick or vomiting
- unusual taste
- diarrhoea (loose stools)
- reduced appetite
- stomach bloating (gas)
- feeling thirsty, dry mouth
- headache
- dizziness
- feeling depressed
- skin itch or rash
- feeling tired
- darkened urine.

Tell your doctor or pharmacist if you notice anything that is making you feel unwell.

Other side effects not listed above may also occur in some people.

After using Zidoval Vaginal Gel

Storage

Keep your tube of Zidoval gel and the vaginal applicators together in their box until it is time to use them.

Keep your pack of Zidoval in a cool dry place where the temperature stays below 25°C.

Exposure to extreme heat or cold can spoil the gel.

Keep it where children cannot reach it.

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

Disposal

If your doctor tells you to stop using this medicine or the expiry date has passed, ask your

pharmacist what to do with any medicine that is left over.

Product description

What it looks like

Zidoval is a colourless to straw-coloured gel, contained in an aluminium tube.

Each tube contains 40g of Zidoval Vaginal Gel.

Ingredients

Each 5 g of Zidoval Vaginal Gel (one full applicator) contains 37.5 mg of metronidazole as the active ingredient.

Other ingredients:

- carbomer 974P
- propylene glycol
- methyl hydroxybenzoate
- propyl hydroxybenzoate
- disodium edetate
- sodium hydroxide
- purified water

Supplier

Zidoval is supplied by:

iNova Pharmaceutical (Australia) Pty. Limited
ABN: 13 617 871 539
Level 10, 12 Help St
Chatswood, NSW 2067
Telephone: 1800 630 056
AUST R 73743

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