

# Zidoval(R) Vaginal Gel

metronidazole 0.75%

## 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. If you need any more information about Zidoval, please ask your doctor or pharmacist.

All medicines have risks and benefits. Your doctor has weighed the risk of you using Zidoval against the benefits it can have for you. If you have any concerns about using this medicine, ask your doctor or pharmacist. Keep this leaflet with the medicine. You may want to read it again.

### Your medicine

The name of your medicine is Zidoval. Zidoval Vaginal Gel contains an active ingredient, metronidazole. Metronidazole is an antibacterial agent. By applying Zidoval Gel directly into the vagina, metronidazole can kill the bacteria at the site of the infection.

### What Zidoval Vaginal Gel is used for

Zidoval Vaginal Gel is used to treat infection of the vagina (bacterial vaginosis) caused by certain bacteria. It is not suitable for all types of vaginal infections.

Zidoval Vaginal Gel is not recommended for use in children (under the age of 12 years), as there have been no studies of its effects in children.

Your doctor may prescribe Zidoval for another purpose. If you are not sure why you are using this medicine ask your doctor.

Your doctor has prescribed this medicine for you only. Do not let someone else use it, as it may be harmful to them.

### Before using Zidoval Vaginal Gel

#### ***When you must not use Zidoval Vaginal Gel***

- \* if you are allergic to metronidazole or to any of the ingredients listed under "Product Description"
- \* if the packaging is torn, shows signs of tampering or after the "use by" date shown on the box or tube.

#### ***Before you start to use Zidoval Vaginal Gel***

Tell your doctor if:

- \* you have a disease of the blood, liver, kidneys or central nervous system.
- \* you are taking medicine to prevent blood clotting (e.g Warfarin)
- \* you are taking lithium or disulfiram or cyclosporin or 5-Fluorouracil

- \* you are taking Carmustine (BCNU) or cyclo-phosphamide.
- \* you are pregnant or you think you are pregnant.
- \* you are breast-feeding

Before using Zidoval Vaginal Gel, you may also wish to discuss with your doctor or pharmacist whether you may consume alcohol while using Zidoval. There have been reports of an unpleasant reaction (flushing, headache, feeling of being sick, fast heart beat) associated with drinking alcohol whilst taking metronidazole tablets by mouth. However, when using Zidoval by vaginal application, only very small amounts of metronidazole are getting into the blood, making any reaction with alcohol unlikely, although it can not be ruled out.

### Using Zidoval Vaginal Gel

#### ***Dosage***

Disposable applicators are provided to help you apply the gel into the vagina. When filled with gel, each applicator contains one single dose (5 g) of Zidoval Vaginal Gel. Insert one applicator full of Zidoval Vaginal Gel into the vagina at bed time. Repeat this procedure using a new applicator at bedtime for 5 consecutive days or as directed by your doctor.

## **How to use Zidoval Vaginal Gel**

Your tube of Zidoval Vaginal Gel is packed in a box which also contains five disposable (throw away) vaginal applicators.

To ensure maximum hygiene, always:

- \* wash your hands before opening the tube or touching the applicators
- \* use a new applicator for each dose
- \* immediately throw away the used applicator in the waste bin

### **1. Opening the tube**

Before using Zidoval Vaginal Gel for the first time, you will need to puncture the metal seal on the tube. To do this, simply unscrew the cap from the tube and pierce the seal using the pointed tip of the cap.

### **2. Filling the applicator**

Step 1: Remove an applicator from the 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.

### **3. 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; alternatively, choose any position you find comfortable.

### **4. 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 throw it in the waste bin immediately.

## **While you are using Zidoval**

- \* Zidoval Vaginal Gel is for vaginal use only. You should not use it in any other way.
- \* Zidoval Vaginal Gel contains ingredients that may cause burning and irritation of the eye. In case of accidental contact with the eye, rinse the eye immediately with plenty of cool tap water.
- \* Zidoval Vaginal Gel may interfere with the results of some blood tests. If you are having any blood tests while using Zidoval, inform the doctor or nurse or technician taking your blood that you are using Zidoval Vaginal Gel which contains metronidazole.
- \* Do not use more than the recommended amount of Zidoval Gel.
- \* If you become pregnant, discuss with your doctor immediately whether or not to continue the therapy.
- \* Do not use Zidoval Vaginal Gel if you are breastfeeding.

## **If you forget to use Zidoval**

If you miss a bedtime dose of Zidoval Vaginal Gel, apply the missed dose as soon as you remember the next morning and then continue to take the next dose at bedtime until the full course, as prescribed by your doctor, has been used.

Do not double the dose at any time to make up for the missed dose. If it is almost the time to apply the next dose when you remember that you have missed a dose, skip the missed dose, apply the next dose at bedtime and continue treatment until the full course, as prescribed by your doctor, has been used.

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## **Side Effects**

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All medicines can have side effects and these may occur with the normal use of Zidoval Vaginal Gel. Tell your doctor as soon as possible if you do not feel well while you are using Zidoval.

There have been reports of the following side effects occurring with Zidoval Vaginal Gel. If the following occur and are severe enough to worry you, tell your doctor.

- \* 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 of being sick, 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

If you experience other side effects or you do not feel well while you are using Zidoval, please tell your doctor.

## **If you use too much Zidoval**

It is important to keep to the dose as prescribed by your doctor. But if you accidentally apply more than one full applicator of Zidoval Vaginal Gel in one day, there is no need to worry. The use of more than one dose in a day is not expected to cause you any problems, although you may be more likely to experience side effects as described above.

If the cream is accidentally swallowed, please contact your nearest hospital casualty department or tell your doctor immediately.

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## **Storage Conditions**

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Keep your tube of Zidoval Vaginal Gel and the vaginal applicators together in their box. Store in a cool dry place where the temperature stays below 25 degrees C. Do not expose to extreme heat or cold which could spoil the gel. As with all medicines, keep Zidoval Vaginal Gel where children cannot reach it.

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## **Product Description**

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### ***What Zidoval Vaginal Gel looks like***

Zidoval Vaginal Gel is a colourless to straw-coloured transparent, slightly hazy gel, packed in an aluminium tube. Each tube contains 40 g of Zidoval Vaginal Gel.

### ***Ingredients***

Each 5 g (full applicator ) of Zidoval Vaginal Gel 0.75% (AUST R 73743) contains 37.5 mg of the active ingredient, metronidazole. Zidoval Vaginal Gel also contains carbomer 974P, propylene glycol, methyl hydroxy benzoate, propyl hydroxy benzoate, disodium edetate, sodium hydroxide and purified water.

### ***Sponsor***

Zidoval Vaginal Gel is distributed in Australia by:

iNova Pharmaceuticals (Australia)  
Pty Limited  
9-15 Chilvers Road, Thornleigh,  
NSW 2120, Australia

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