

Package leaflet: Information for the user

Zidoval 7.5 mg/g Vaginal Gel Metronidazole

Read all of this leaflet carefully before you start using this medicine because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.
- In this leaflet, Zidoval 7.5 mg/g Vaginal Gel is called Zidoval gel.

What is in this leaflet

1. What Zidoval gel is and what it is used for
2. What you need to know before you use Zidoval gel
3. How to use Zidoval gel
4. Possible side effects
5. How to store Zidoval gel
6. Contents of the pack and other information.

1. What Zidoval gel is and what it is used for

Zidoval gel belongs to a group of medicines called antibacterials. These work by killing many kinds of bacteria that cause infections.

Zidoval gel is used to treat an infection of the vagina (called bacterial vaginosis or BV for short) in adults. Zidoval gel is applied inside the vagina where it destroys the bacteria at the site of the infection.

It is important that bacterial vaginosis is treated and cleared completely otherwise the infection can come back. You must take the full course of this medicine as prescribed by your doctor to prevent this from happening.

2. What you need to know before you use Zidoval gel

Do not use Zidoval gel if:

- You are allergic to metronidazole or any of the other ingredients of this medicine (listed in section 6).
- You are allergic to any similar nitroimidazole antibacterials
- You are allergic to parabens (a preservative agent)

If any of the above applies to you talk to your doctor or pharmacist.

Warnings and precautions

Talk to your doctor or pharmacist before using Zidoval gel:

- If you have ever had any blood problems or a disease affecting the blood
- 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
- If you are having your period
- If you are having blood tests because metronidazole can interfere with the results of some tests
- Avoid prolonged and unnecessary use of this medicine.

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

Children and adolescents

Zidoval gel is not recommended for use in children under 18 years of age because the medicine's safety in these groups has not been established.

Elderly

Zidoval gel is not recommended for use in the elderly because the medicine's safety in this group has not been established.

Other medicines and Zidoval gel

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

Zidoval gel may increase the effect that the following medicines have:

- Coumarin anticoagulants (e.g. warfarin), which are medicines used to prevent blood clotting
- Lithium, a medicine to treat mental illness
- Cyclosporin, a medicine used to treat autoimmune diseases and rheumatoid arthritis
- 5-fluorouracil, a medicine used for skin problems and the treatment of cancer
- Any other medicine, including medicines obtained without a prescription.

Zidoval gel with alcohol

Drinking alcohol whilst using Zidoval gel may make you feel or be sick, become confused, have a headache or have an abnormally fast heart beat. If this happens, stop drinking alcohol and consult your doctor or pharmacist.

Pregnancy and breast-feeding

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

Zidoval gel contains methyl parahydroxybenzoate (E218) and propyl parahydroxybenzoate (E216) which may cause allergic reactions (possibly delayed).

Zidoval gel also contains 30 mg propylene glycol (E1520) in each gram. Propylene glycol may cause skin irritation.

3. How to use Zidoval gel

Always use this medicine exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure.

Zidoval gel is for vaginal use only.

Important:

Your doctor will choose the dose that is right for you. Your dose will be shown clearly on the label that your pharmacist puts on your medicine. If it does not, or you are not sure, ask your doctor or pharmacist.

Before you apply Zidoval gel

Good hygiene whilst using Zidoval gel is very important. Always:

- Wash your hands before opening the tube or touching the applicators
- Use a fresh applicator for each dose.
- Immediately throw away each used applicator in the waste bin.

Adult dose

- The dose of Zidoval gel is one 5 g application inserted into the vagina once daily, at bedtime, for five consecutive days.

Use in children and adolescents

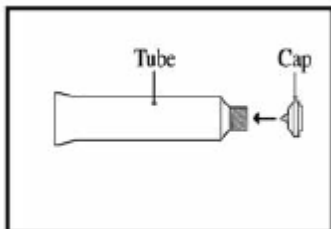
This medicine is not recommended for use by children under 18 years of age.

Use in the elderly

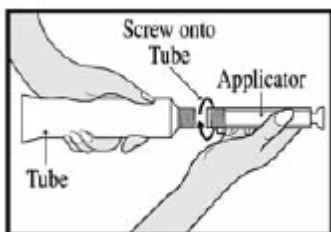
This medicine is not recommended for use by the elderly.

Instructions for use

- Disposable (throw away) applicators are provided with Zidoval gel to help you put the gel into your vagina
- **Opening the tube:** Remove the cap from the tube of Zidoval gel and pierce the sealed end of the tube with the pointed end of the cap



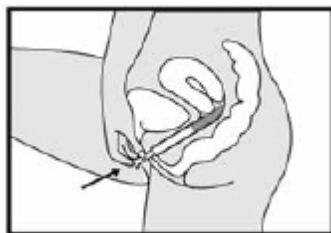
- **Filling the applicator:** Screw the open end of an applicator on to the end of the open tube. Squeeze the tube gently and slowly from the bottom to fill the applicator. The plunger will move as the applicator fills and will stop moving when it holds the required 5 g dose of Zidoval gel. Remove the applicator from the tube and replace the cap on the tube



- **Inserting the applicator:** Hold the filled applicator by its barrel and gently insert the applicator into the vagina as far as it will comfortably go. You may find this is easiest to do whilst lying on your back with your knees bent



- **Releasing the gel:** Slowly push the plunger down into the applicator to release the gel into your vagina. Continue pressing down 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.

Repeat this procedure using a fresh applicator at bedtime for five consecutive days, or as directed by your doctor. If after using the full 5-day course of Zidoval gel you don't feel better, you should see your doctor again.

If you use more Zidoval gel than you should

Do not use more Zidoval gel than you should. If you accidentally use too much ask your doctor or pharmacist for advice. Using too much of this medicine can increase the risk of side effects (see Section 4 below).

If you forget to use Zidoval gel

Do not take a double dose to make up for a forgotten dose. Apply Zidoval gel at your next bedtime.

If you stop using Zidoval gel

Do not stop using Zidoval gel during a 5-day course of treatment without first talking to your doctor. It is important that you take the full course so that your infection clears up completely.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

Common side effects (may affect up to 1 in 10 people)

- Headache and dizziness
- Stomach cramps
- Being sick
- Unpleasant taste in your mouth
- Unusual feeling on your tongue
- Dry skin
- Redness of the skin (erythema)
- Itching of the skin (pruritus)
- Skin discomfort (burning, pain of skin / stinging)
- Skin irritation
- Vaginal thrush (candidiasis)
- Vaginal discharge
- Discomfort around your pelvis
- Decreased appetite.

Uncommon side effects (may affect up to 1 in 100 people)

- Feeling sick
- Depression
- Tiredness
- Feeling irritable
- Difficulty in sleeping
- An unusual feeling in your fingers and toes
- Diarrhoea
- Constipation
- Bloating or gurgling stomach
- A dry mouth or feeling thirsty
- Metallic taste in your mouth
- Muscle cramps
- Darkened urine
- Urinary tract infections (UTIs) that may cause pain or a burning sensation when you pass water, or may make you need to pass water more often or more urgently
- Swelling of your vulva (the outside of your vagina)
- Changes in your periods such as spotting or bleeding between periods or increased discomfort during your period.

The following side effect has also been reported (frequency not known)

- An itchy rash (urticaria).

Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly **via the national reporting system listed in Appendix V***. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Zidoval gel

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the carton and tube after EXP. The expiry date refers to the last day of that month.

Do not store above 25°C.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What Zidoval gel contains

- The active substance is metronidazole. Each gram of gel contains 7.5 mg of metronidazole.
- The other ingredients are: Carbopol 974P, disodium edetate, methyl parahydroxybenzoate (E218), propyl parahydroxybenzoate (E216), propylene glycol (E1520), sodium hydroxide (E524) and purified water.

What Zidoval gel looks like and contents of the pack

Zidoval Vaginal gel is colourless or straw coloured. It comes in a 40 g aluminium tube with a screw on plastic cap in a carton. The carton also contains 5 disposable vaginal applicators that deliver 5 g of gel.

Marketing Authorisation Holder

[To be completed nationally]

Manufacturer

Meda Manufacturing, Avenue JF Kennedy, 33700 Merignac, France.

This leaflet was last revised in MM/YYYY.

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