PATIENT PACKAGE INSERT IN ACCORDANCE WITH THE PHARMACISTS' REGULATIONS (PREPARATIONS) - 1986

This medicine is dispensed with a physician's prescription only

Zidoval 7.5 mg/g Vaginal Gel
Vaginal Gel

Composition:
Active ingredient: metronidazole 7.5 mg/g

For the list of inactive ingredients and allergens in the preparation, see section 6, "Additional information".

1. What is this medicine intended for?

Zidoval 7.5 mg/g Vaginal Gel is indicated for the treatment of bacterial vaginosis (formally called nonspecific vaginitis gardnella vaginalis vaginitis or haemophilus vaginitis).

Therapeutic group: Antibacterial from the nitroimidazole group.

2. Before using the medicine:

Do not use this medicine if:
- You are allergic to the active ingredient metronidazole or to any of the additional ingredients that the medicine contains (listed in section 6, "Additional information").
- You are allergic to any antibacterial substance belonging to the nitroimidazole group or to similar antibacterials.
- You are allergic to parabens (a preservative agent).

Special warnings regarding the use of the medicine:
Before starting treatment with Zidoval 7.5 mg/g Vaginal Gel, tell your physician if:
- In the past you have suffered from problems of the blood system or a disease affecting the blood.
- You have or think you may have vaginal candidiasis: The symptoms of vaginal candidiasis may become more noticeable when you use **Zidoval 7.5 mg/g Vaginal Gel** and you may require additional treatment for dealing with the symptoms.
- You are having your period.
- You are about to have laboratory tests, because metronidazole may interfere with the results.
- Avoid prolonged and unnecessary use of this medicine.

As with all vaginal infections, you should avoid sexual intercourse during the period of infection and while you are using **Zidoval 7.5 mg/g Vaginal Gel**.

Children and adolescents:
Zidoval 7.5 mg/g Vaginal Gel is not recommended for use by girls under the age of 18 because the efficacy and safety of use by this age group is unknown.

Elderly:
Vaginal bacterial infections are uncommon in the elderly population and therefore no clinical assessment has been carried out regarding the use of **Zidoval 7.5 mg/g Vaginal Gel** by this age group.

Drug interactions:
If you are taking, or have recently taken, any other medicines, including non-prescription medicines or nutritional supplements, tell your physician or pharmacist. Particularly if you are taking:
- Anticoagulants such as Coumarin: warfarin.
- A medicine to treat mental illness: lithium.
- Medicines for the treatment of autoimmune diseases and rheumatoid arthritis: cyclosporin.
- A medicine used for skin problems and cancer treatment: 5-fluorouracil.

Use of the medicine and alcohol consumption:
Drinking alcohol during treatment with **Zidoval 7.5 mg/g Vaginal Gel** may cause you to experience sickness, confusion, headaches or heart palpitations. If any of these effects occur, stop drinking alcohol and consult your physician or pharmacist.

Pregnancy, breastfeeding and fertility:
If you are pregnant or breastfeeding, think that **you may be pregnant** or are planning a pregnancy, consult your physician before using **Zidoval 7.5 mg/g Vaginal Gel**.

Driving and operating machinery:
Zidoval 7.5 mg/g Vaginal Gel has no effect on driving ability or the operation of machinery.

Important information about some of the medicine's ingredients:
Zidoval 7.5 mg/g Vaginal Gel contains
methyl parahydroxybenzoate (E218) - 0.8 mg/g
propyl parahydroxybenzoate (E216) - 0.2 mg/g
which may cause allergic reactions.
Zidoval 7.5 mg/g Vaginal Gel also contains:
propylene glycol (E1520) - 30 mg/g
which may cause skin irritation.

3. How should you use the medicine?

Always use this preparation according to your physician's instructions. You should check with your physician or pharmacist if you are unsure about the dosage or treatment regimen of the preparation. The dosage and treatment regimen will be determined by your physician only .
The usual dose, in the absence of any other instruction from your physician, is generally:
For women over the age of 18: One applicator, once daily, at bedtime, for five days.

Do not exceed the recommended dose.

Instructions for using the medicine:

1. Filling the applicator
Remove the cap from the tube and pierce the metal seal with the pointed end of the cap.
Screw the applicator onto the tube.
Gently squeeze gel from the tube into the applicator. The applicator plunger will move during filling of the applicator and will stop when the applicator contains the required amount of gel.
Unscrew the applicator and replace the cap on the tube.

2. Inserting the applicator
The applicator may be inserted while laying on your back with your knees bent, or in any other comfortable position.
Hold the filled applicator plunger and gently insert it deep into the vagina in a manner that will not cause discomfort.
Gently press the plunger until it stops, indicating that all the applicator contents are in the vagina. Remove the applicator and discard it in the waste bin.

3. Maintenance of the applicator
Each applicator is intended for single use. If your physician has recommended treatment twice daily, the same applicator may be reused.
Remove the plunger from the applicator after use.
Wash the plunger and applicator in warm soapy water and rinse thoroughly with water.
In order to allow repeat use of the applicator, gently push the plunger back into the applicator.

If you have accidentally applied a higher dosage or if a child has accidentally swallowed the medicine, proceed immediately to a hospital emergency room and bring the package of medicine with you.

Using too much of this medicine can increase the risk of side effects (see section 4 "Side effects").

If you forgot to apply the medicine at the required time, apply the next dose before bedtime. Do not apply more than once a day.

Adhere to the treatment regimen recommended by your physician.

If you stop taking the medicine
Do not stop taking **Zidoval 7.5 mg/g Vaginal Gel** during the five days of treatment without consulting with your physician. It is important that the vaginal inflammation is completely treated, otherwise the infection may reoccur. You must follow the entire course of treatment as prescribed by your physician in order to prevent recurrence of the infection.

Do not take medicines in the dark! Check the label and the dose each time you take a medicine. Wear glasses if you need them.

If you have further questions regarding use of the medicine, consult your physician or pharmacist.

How can you contribute to the treatment's success?
Wear cotton underwear only and change frequently. Pantyhose must also be changed daily. Infection of your partner is possible. Therefore, during the period of treatment, you should either avoid sexual contact or be strict about condom use during sexual contact. Furthermore, you should consult your physician about the need for your partner to also receive treatment.
If you are using a vaginal douche between treatments, be careful not to inject the irrigating fluid in an excessive amount or at high pressure. This is to avoid injecting it into the uterus, which may result in the infection's spread. If you are pregnant - do not use any douches.

4. Side effects:

As with any medicine, the use of **Zidoval 7.5 mg/g Vaginal Gel** may cause side effects in some users. Do not be alarmed when reading the list of side effects. You may not suffer from any of them.

Common side effects - effects that occur in 1-10 of 100 users:
- Headache and dizziness
- Stomach cramps
- Sickness
- Unpleasant taste in the mouth
- Unusual feeling on your tongue
- Dry skin
- Redness of the skin (erythema)
- Itching of the skin (pruritus)
- Skin discomfort (burning, painful skin / stinging)
- Skin irritation
- Vaginal candidiasis
- Vaginal discharge
- Discomfort around your pelvis
- Decreased appetite

Uncommon side effects - effects that occur in 1-10 of 1000 users:
- Feeling sick
- Depression
- Tiredness
- Feeling irritable
- Difficulty sleeping
- An unusual feeling in your fingers and toes
- Diarrhoea
- Constipation
- Bloated and gurgling stomach
- A dry mouth or feeling thirsty
- Metallic taste in your mouth
- Muscle cramps
- Dark urine
- Urinary tract infections (UTI) that may cause pain or a burning sensation when urinating, or more frequent urination
- Swelling of the vulva (the external part of the female genitalia)
- Changes in your periods such as bleeding between periods or increased discomfort during your period

Side effects of unknown frequency (cannot be determined from the known data):
- An itchy rash (urticaria)

If a side effect occurs, if one of the side effects worsens or if you suffer from a side effect not mentioned in this leaflet, consult your physician.

Side effects can be reported to the Ministry of Health by clicking the link "Report Side Effects of Drug Treatment" on the homepage of the Ministry of Health website (www.health.gov.il), which directs you to the online form for reporting side effects, or by entering the link: https://sideeffects.health.gov.il.

5. How should the medicine be stored?

- Avoid poisoning! This medicine, and any other medicine, should be kept in a closed place out of the reach and sight of children and/or infants, in order to avoid poisoning. Do not induce vomiting unless explicitly instructed to do so by a physician.
- Do not use this medicine after the expiry date (exp. date) which appears on the package. The expiry date refers to the last day of that month.

Storage conditions:
- Store at a temperature below 25^0C.
- Do not dispose of medicines via wastewater or household waste. Ask your pharmacist how to dispose of medicines that are no longer in use. These measures will help protect the environment.

6. Additional information:

- In addition to the active ingredient, metronidazole, this medicine also contains:
  propylene glycol, carbomer (carbopol 974P), methyl parahydroxybenzoate, disodium edetate, propyl parahydroxybenzoate, sodium hydroxide, purified water
- What the medicine looks like and what the package contains:
  Zidoval 7.5 mg/g Vaginal Gel is a colourless or straw coloured gel. The gel comes in a 40 gram aluminium tube with a plastic screw-on cap in a carton. The carton also contains 5 disposable applicators that deliver 5 g of gel.
- **Registration Holder:** Megapharm Ltd., P.O.B. 519, Hod Hasharon, 4510501, Israel.
- **Manufacturer:** Meda Manufacturing, Merignac, France.
- Updated in September, 2020.
- **Registration number of the medicine in the National Drug Registry of the Ministry of Health: Zidoval 7.5 mg/g Vaginal Gel**: 118 72 29887