PATIENT INFORMATION LEAFLET

SCHEDULING STATUS:

S2

METROGEL V, Vaginal Gel

Metronidazole

Read all of this leaflet carefully because it contains important information for you

METROGEL V is available without a doctor's prescription, for you to treat a mild illness. Nevertheless, you still need to use METROGEL V carefully to get the best results from it.

Keep this leaflet. You may need to read it again.

Do not share METROGEL V with any other person.

Ask your healthcare provider or pharmacist if you need more information or advice.

You must see a doctor if your symptoms worsen or do not improve after 5 days.

What is in this leaflet

1. What METROGEL V is and what it is used for

2. What you need to know before you use METROGEL V

3. How to use METROGEL V

4. Possible side effects

5. How to store METROGEL V

6. Contents of the pack and other information

1. What METROGEL V is and what it is used for

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

METROGEL V is used to treat an infection of the vagina (called bacterial vaginosis or BV for short) in adults. METROGEL V 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 METROGEL V

Do not use METROGEL V

You are allergic to metronidazole or any of the other ingredients of this METROGEL V (listed in section 6).

Warnings and precautions

Take special care with METROGEL V:

- 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 METROGEL V 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 with METROGEL V
- Cockayne Syndrome (CS) is a rare form of dwarfism

You should avoid sexual intercourse during the infection and whilst you are using METROGEL V.

Children and adolescents

METROGEL V is not recommended for use because the medicine's safety in these groups has not been established.

Other medicines and METROGEL V

Always tell your healthcare provider if you are taking any other medicine. (This includes all complementary or traditional medicines.)

METROGEL V may increase the effect that the following medicines have:

- Coumarin anticoagulants, such as warfarin, which are used to prevent blood clotting
- Lithium, a medicine to treat mental illness.

METROGEL V with food and alcohol

Drinking alcohol whilst using METROGEL V 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, breastfeeding and fertility

If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist or other healthcare provider for advice before using METROGEL V.

Driving and using machines

It is not always possible to predict to what extent METROGEL V may interfere with your daily activities. You should ensure that you do not engage in the above activities until you are aware of the measure to which METROGEL V affects you.

METROGEL V contains preservatives

METROGEL V contains methyl parahydroxybenzoate (E218) and propyl parahydroxybenzoate which may cause allergic reactions.

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

3. How to use METROGEL V

Do not share medicines prescribed for you with any other person.

Always use METROGEL V exactly as described in this leaflet or as your doctor, or pharmacist or nurse has told you. Check with your doctor or, pharmacist or nurse if you are not sure.

Before you apply METROGEL V:

Good hygiene whilst using METROGEL V 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 METROGEL V is one 5 g application inserted into the vagina once daily, at bedtime, for five consecutive days.

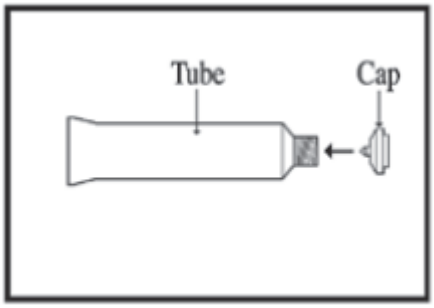
Use in children and adolescents

This medicine is not recommended for use by children.

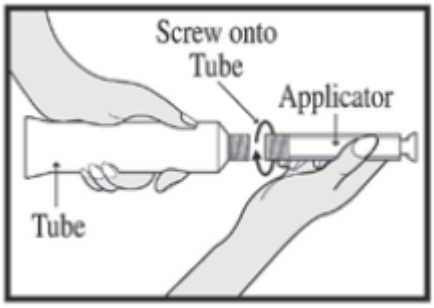
Instructions for use

Disposable (throw away) applicators are provided with METROGEL V to help you put the gel into your vagina

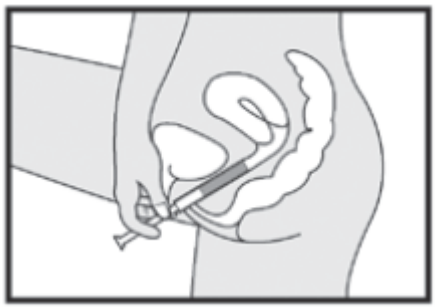
Opening the tube: Remove the cap from the tube of METROGEL V and pierce the sealed end of the tube with the pointed end of the cap



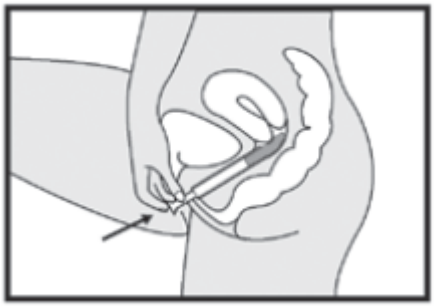
Filling the applicator: Screw the open end of an applicator on to the end of the open tube. Squeeze the tube gently and slowly from the bottom to fill the applicator. The plunger will move as the applicator fills and will stop moving when it holds the required 5 g dose of METROVAL V. Remove the applicator 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 laying 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 METROGEL V you don‘t feel better, you should see your doctor again.

If you use more METROGEL V than you should

In the event of overdosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison centre.

If you forget to use METROGEL V

Do not receive a double dose to make up for forgotten individual doses.

4. Possible side effects

METROGEL V can have side effects.

Not all side effects reported for METROGEL V are included in this leaflet. Should your general health worsen or if you experience any untoward effects while using METROGEL V, please consult your healthcare provider for advice.

If any of the following happens, stop using METROGEL V and tell your doctor immediately or go to the casualty department at your nearest hospital:

- swelling of the hands, feet, ankles, face, lips and mouth or throat, which may cause difficulty in swallowing or breathing,

- rash or itching,
- fainting.

These are all very serious side effects. If you have them, you may have had a serious reaction to METROGELV. You may need urgent medical attention or hospitalisation.

Tell your doctor immediately or go to the casualty department at your nearest hospital if you notice any of the following:

- vaginal thrush, burning/swelling/itching
- vulvovaginitis, swelling or infection of the vulva and vagina
- vaginal discharge
- discomfort around your pelvis

These are all serious side effects. You may need urgent medical attention.

Tell your doctor if you notice any of the following:

- headache and dizziness
- stomach cramps
- being sick
- unpleasant taste in your mouth
- unusual feeling on your tongue
- constipation
- diarrhoea
- metallic taste in your mouth
- decreased appetite
- bloated or gurgling stomach
- a dry mouth or feeling thirsty
- feeling sick
- tiredness
- an unusual feeling in your fingers and toes

- feeling irritable
- difficulty in sleeping
- 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
- hives
- skin discomfort (burning, pain of skin/stinging)

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

Reporting of side effects

If you get side effects, talk to your doctor or, pharmacist or nurse. You can also report side effects to SAHPRA via the "**6.04 Adverse Drug Reaction Reporting Form",** found online under SAHPRA's publications: https://www.sahpra.org.za/Publications/Index/8. By reporting side effects, you can help provide more information on the safety of METROGEL V.

5. How to store METROGEL V

Keep all medicines out of reach of children.

Store at or below 30 °C.

Do not use after the expiry date stated on the carton.

Return all unused medicine to your pharmacist.

Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

6. Contents of the pack and other information

What METROGEL V contains

Each 5 g contains 35,5 mg metronidazole.

The other ingredients are carbomer, edetate disodium, methylparaben, propylene glycol, propylparaben, sodium hydroxide and purified water.

What METROGEL V looks like and contents of the pack

A colourless to straw-coloured, transparent, slightly hazy, single-phase gel.

Aluminium tubes with polyethylene screw caps containing 40 g product. The product is packed with five, 5 g vaginal applicators.

Holder of Certificate of Registration

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