

Approved Patient Information Leaflet for Medicines for Human Use:

BETADINE® VAGINAL GEL

SCHEDULING STATUS S2

BETADINE® VAGINAL GEL (10 % gel)

Povidone-iodine

Read all of this leaflet carefully before you start using BETADINE® VAGINAL GEL because it contains important information for you

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor, pharmacist, nurse or other health care provider.
- BETADINE® VAGINAL GEL has been prescribed for you personally and you should not share your medicine with other people. It may harm them, even if their symptoms are the same as yours.

What is in this leaflet

1. What BETADINE® VAGINAL GEL is and what it is used for
2. What you need to know before you use BETADINE® VAGINAL GEL
3. How to use BETADINE® VAGINAL GEL
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1. What BETADINE® VAGINAL GEL is and what it is used for

BETADINE® VAGINAL GEL contains povidone-iodine, an antiseptic, which kills a wide range of germs.

BETADINE® VAGINAL GEL is used for:

Disinfection of the vagina before and after operations.

In acute and chronic vaginal infections such as bacterial vaginosis and fungal infections, viral infections (such as genital herpes).

Fungal infections, also after antibiotic or corticosteroid therapy in case of complications.

2. What you need to know before you use BETADINE® VAGINAL GEL

Do not use BETADINE® VAGINAL GEL:

- if you are hypersensitive (allergic) to povidone-iodine or any of the other ingredients of BETADINE® VAGINAL GEL (listed in section 6)
- if you have an enlarged thyroid gland or any conditions affecting your thyroid
- if you are taking products containing mercury, as this can cause skin damage
- in pre-pubertal children
- if you are taking a medicine called lithium
- before, during and after radioiodine testing or treatment

Warnings and precautions

You should not use BETADINE® VAGINAL GEL on large areas of the skin and not for longer than 10 days, unless your doctor or healthcare provider has told you to.

Take special care with BETADINE® VAGINAL GEL

- if you are pregnant or breastfeeding (see below)
- if BETADINE® VAGINAL GEL is applied regularly to broken skin, particularly if you have kidney disease.
- if you are going to have thyroid function tests, as these may be affected by using BETADINE® VAGINAL GEL. Allow a period of 4 weeks after BETADINE® VAGINAL GEL treatment before commencing treatment.
- to avoid solutions containing a detergent if you are treating the vaginal area with BETADINE® VAGINAL GEL.

- if you have an allergic or irritant reaction such as redness, small blisters, itching or a rash. If this happens, you should stop using BETADINE® VAGINAL GEL.
- if you are planning to have tests to detect blood in faeces or blood in urine, as the BETADINE® VAGINAL GEL may produce false-positive results.
- BETADINE® VAGINAL GEL may be spermicidal (may kill sperm) and should not be used if you want to become pregnant.
- BETADINE® VAGINAL GEL can cause temporary skin discoloration.

Children and adolescents

Do not use on pre-pubertal children.

Other medicines and BETADINE® VAGINAL GEL

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

In particular you should tell your doctor or pharmacist if you are taking the following:

- Lithium (for depression).
- wound-treatment medicines containing enzymes, silver, hydrogen peroxide and taurolidine
- antiseptics containing octenidine.

Tell your doctor if you are due to have a thyroid test, faeces (stool) or urine test, as BETADINE® VAGINAL GEL may affect the results, for up to 4 weeks following treatment.

Pregnancy and breastfeeding

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 health care provider for advice before using this medicine.

BETADINE® VAGINAL GEL may be spermicidal (may kill sperm) and should not be used if you want to become pregnant.

Driving and using machines

BETADINE® VAGINAL GEL has no known effect on the ability to drive and use machines.

3. How to use BETADINE® VAGINAL GEL

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

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

For use in the vagina only.

Adults and elderly females

Treatment of vaginal infections

Insert one applicator-full of BETADINE® VAGINAL GEL every day at bedtime, including days of the menstrual cycle. Treatment must be done on a daily basis.

Apply BETADINE® VAGINAL GEL in the evening and allow to remain in the vagina overnight.

BETADINE® VAGINAL GEL may also spread thinly 1 - 2 cm around the external genital area two or three times a day.

Duration of treatment for infections

Use for 5 – 10 days. Treatment must only be extended if instructed by your healthcare professional.

Preoperative vaginal disinfection

Apply BETADINE® VAGINAL GEL in the evening before the operation, as for the treatment of vaginitis and leave in the vagina overnight. On the next morning the vagina may be flushed with BETADINE® DOUCHE before surgery.

Method of administration

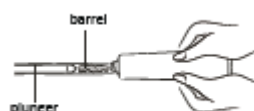
Remove cap from tube and puncture the metal seal on the tube with the pointed tip of the cap.



Screw the applicator onto the thread on the tube.



Pull plunger back to limit and fill the applicator with BETADINE® VAGINAL GEL by applying pressure to the bottom of tube, forcing the gel into the applicator barrel.



Once filled, unscrew the applicator from the tube and replace the tube cap.

In a reclining position, gently insert vaginal applicator high into the vagina and depress plunger to deposit BETADINE® VAGINAL GEL. Carefully remove the applicator, keeping the plunger depressed.



Rinse the applicator with warm running water and allow to air dry.



The use of a sanitary pad is recommended during treatment to prevent staining.

If you use more BETADINE® VAGINAL GEL than you should

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

Systemic absorption of iodine from BETADINE® VAGINAL GEL after repeated application to large areas

iNova Pharmaceuticals (Pty) Ltd, 510531, BETADINE® VAGINAL GEL, povidone-iodine 10 % w/w

of wounds or burns or deliberate or accidental ingestion of large quantities may lead to a number of overdose effects: metallic taste in mouth, increased saliva production, burning or pain in the throat or mouth, irritation and swelling of the eyes, pulmonary oedema (fluid in the lungs, making it difficult to breathe), skin reactions, upset stomach and diarrhoea, fast heart rate, low blood pressure, fever, metabolic acidosis (high levels of acid in the body), high levels of sodium in the blood (seen with a test) and kidney problems.

If you experience any of the effects listed above, following the use of BETADINE® VAGINAL GEL, or following deliberate or accidental ingestion, you should contact your doctor, pharmacist or local hospital immediately. Take this leaflet and any other packaging with you so they know what you have been using.

If you forget to use BETADINE® VAGINAL GEL

Do not use a double dose to make up for a forgotten dose, simply use the next dose as planned then carry on as before.

4. Possible side effects

BETADINE® VAGINAL GEL can have side effects.

Not all side effects reported for BETADINE® VAGINAL GEL are included in this leaflet. Should your general health worsen or if you experience any untoward effects while using BETADINE® VAGINAL GEL, please consult your health care provider for advice.

If any of the following happens, stop using BETADINE® VAGINAL GEL and tell your doctor immediately or go to the casualty department at your nearest hospital:

- Allergic type reactions that occur quickly and include an itchy raised skin rash (hives), a body rash, severe inflammation of the skin surface, sudden breathing problems, feeling faint, swelling of the mouth, face, lips, tongue and throat.

- Thyroid problems, symptoms may include feeling nervous, moody, difficulty sleeping, hand tremors, fast or irregular heartbeat, trouble breathing, feeling very hot or sweaty, and weight loss.

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

Tell your doctor if you notice any of the following:

Less frequent side effects

- Skin redness and / or skin swelling, itching, small blisters.

The frequency of the following side effects is unknown

- Hypothyroidism (insufficient function of thyroid gland, which can cause fatigue, weight gain, slow heart rate) - can occur due to prolonged or extensive use of BETADINE® VAGINAL GEL.
- The amount of electrolytes in your body is too high or too low (seen in a test) – can occur when large amounts of BETADINE® VAGINAL GEL are used.
- Increased amount of acid in your blood (the main symptoms are shortness of breath, confusion and lethargy) – can occur when large amounts of BETADINE® VAGINAL GEL are used.
- Kidney failure (symptoms include difficulty urinating, thirst and a dry mouth, and pain on one side of your back) – can occur when large amounts of BETADINE® VAGINAL GEL are used.
- Changes in the chemical properties of the blood serum may occur (seen in a test) after absorption of large amounts of BETADINE® VAGINAL GEL.
- Spermicidal effect (may kill sperm), therefore you should not use BETADINE® VAGINAL GEL if you want to become pregnant.
- Dry skin.
- Skin discoloration.
- Chemical skin burns.

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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, pharmacist or nurse. You can also report side effects to SAHPRA via the Med Safety APP (Medsafety X SAHPRA) and eReporting platform (who-umc.org) found on SAHPRA website. By reporting side effects, you can help provide more information on the safety of BETADINE® VAGINAL GEL.

Alternately contact iNova Pharmaceuticals at +27 11 087 0000.

Website: www.inovapharma.co.za

5. How to store BETADINE® VAGINAL GEL

Store at or below 30 °C.

Store all medicines out of reach of children.

Return all unused medicine to your pharmacist. Do not dispose of unused medicines in drains or sewerage systems (i.e. toilets).

6. Contents of the pack and other information

What BETADINE® VAGINAL GEL contains

Each 1 g contains 100 mg povidone-iodine (10 % w/w).

The other ingredients are Macrogol 400, Macrogol 4000, Purified Water Ph Eur, Sodium Bicarbonate.

What BETADINE® VAGINAL GEL looks like and contents of the pack

BETADINE® VAGINAL GEL is a smooth uniform dark brown gel/ointment.

BETADINE® VAGINAL GEL is packed in an aluminium tube with an internal lacquer lining (Protaral®), with a polypropylene (PP) or heterophasic copolymer screw cap.

Pack size: 100 g

Holder of Certificate of Registration

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Access to the corresponding Professional Information

Full Professional Information can be found at <https://inovapharma.co.za/brands-and-products/professional-information/> or can be obtained upon request from iNova Pharmaceuticals.

Please scan the QR code



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