

Package leaflet: Information for the user

BETADINE® Vaginal Douche 10%w/v

Povidone-Iodine

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, pharmacist, or nurse.
- If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What **BETADINE® Vaginal Douche** is and what it is used for
2. What you need to know before you use **BETADINE® Vaginal Douche**
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4. Possible side effects
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6. Contents of the pack and other information

1. What BETADINE® Vaginal Douche is and what it is used for

BETADINE® Vaginal Douche is an antiseptic containing Povidone-Iodine, which is broad-spectrum germicide (destructive to germs). It is effective for all vaginal infection. It offers rapid relief of symptoms such as burning or irritation.

It is used as a vaginal cleanser for the treatment of vaginitis (inflammation of the vagina) due to candidal, trichomonal, non-specific or mixed infections and for preoperative disinfection of the vagina.

2. What you need to know before you use BETADINE® Vaginal Douche

- If you are allergic to Povidone-Iodine or any of the other excipients of this medicine (listed in section 6).
- In patients hypersensitive to iodine or any other of the excipients listed in section 6.
- In patients with thyroid disorders (in particular nodular colloid goiter, endemic goiter and Hashimoto's thyroiditis).
- In patients taking lithium.
- In pre-pubertal children.
- before, during and after radio-iodine administration.
- in patients using products containing mercury.

Warnings and precautions

Talk to your doctor, pharmacist or nurse before using **BETADINE® Vaginal Douche**

- Special caution is needed when regular applications to broken skin are made to patients with pre-existing renal insufficiency.
- Avoid solutions containing a vaginal detergent if treating vaginal area with Povidone-Iodine.
- Thyroid function tests may be affected using products containing iodine.
- Contamination with Povidone-Iodine of several tests for detecting occult blood in faeces or blood in urine may produce false-positive results.
- The product is spermicidal and should not be used when consumption is desired.

Pregnancy, breast-feeding and fertility

BETADINE® Vaginal Douche should only be used under medical prescription. Povidone Iodine passes into the placenta and is secreted in breast milk. Povidone Iodine use should be avoided unless the potential benefit to the mother justifies the potential risk to the foetus and neonate or if a safer alternative is unavailable. 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.

Fertility

There are limited human fertility data for Povidone iodine. No data are available on fertility outcomes.

Children and adolescents

Do not use in pre-pubertal children.

Driving and using machines

No such influence has been reported.

Other medicines and BETADINE® Vaginal Douche

- The concomitant use of wound-treatment preparations containing enzymatic component leads to a weakening of the effects of both substances. Products containing mercury, silver, hydrogen peroxide, and taurididine may interact with povidone-iodine and should not be used concomitantly.
- Simultaneous use with mercury products may lead to the formation of a substance which can damage the skin.
- Using this treatment may interfere with tests of thyroid function and can make a planned treatment of the thyroid with iodine impossible. After the end of the treatment 4 weeks should be allowed before a new scintigram is carried out.
- Several types of tests for detecting occur (not visible) blood in faeces or blood in urine may be affected (i.e. produce false-positive results).
- Povidone-iodine products when used before or after application of octenidine may lead to transient dark discolourations at the application site
- Povidone-iodine use could lead to transient skin discolouration at the application site caused by the drug products own colour.

3. How to use BETADINE® Vaginal Douche

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

Use in Adults and Elderly

Intravaginal use.

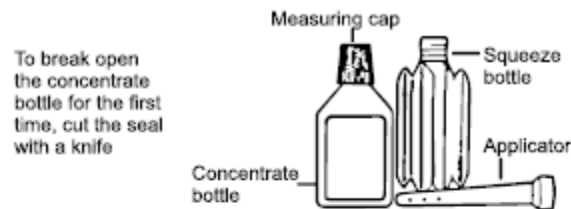
Use once a day preferably in the morning for up to 14 days (including days of the menstrual cycle) or as directed by the doctor.

- Add two measuring capfuls of the concentrate to the squeeze bottle.
- Fill the squeeze bottle with lukewarm water.
- Screw the applicator to the squeeze bottle and shake gently.
- Carefully insert the applicator high into the vagina without causing discomfort. Expel as much cleansing liquid as possible by gentle pressure on the sides of the squeeze bottle allowing solution to run freely from the vagina.
- Remove the applicator from the vagina allowing air to enter the squeeze bottle so that it regains its original shape.
- Re-insert the applicator into the vagina squeezing once again to cleanse the vagina thoroughly.
- Repeat until all the **BETADINE® Vaginal Douche** solution has been used.
- Finally rinse away the excess solution from around the vagina with a clean sponge or flannel. Dry the vaginal area with a clean cloth or paper towel.
- Use warm water to clean the empty bottle and applicator and store for future use.

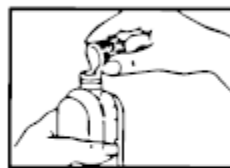
Use in children and adolescents

Do not use in pre-pubertal children.

BETADINE® Vaginal Douche is well tolerated. It can be removed with water and soap and stains neither the skin nor most fabrics. In most cases marks can be removed from nylon items with a dilute solution of ammonia.



Measure 2 capfuls of the liquid, using the measuring cap of the concentrate bottle.



Tip the measured liquid, into the squeeze bottle.



Fill the squeeze bottle to the neck with lukewarm water.



Screw the applicator onto the squeeze bottle



To expel the contents of the squeeze bottle, gently squeeze the sides with both hands.

Three recommended methods of using the product:
Decide which method of insertion is easiest for you.
It's important to be in a relaxed and uncramped position.



1. In the bath



2. On the toilet or bed



3. In the shower

If you forget to use BETADINE® Vaginal Douche

If you forget to use your medication, use it as soon as you remember unless it's time for the next application. Then follow the original instructions for use. Do not use a double dose to make up for the forgotten dose.

If you stop using BETADINE® Vaginal Douche

The duration of treatment is decided by your doctor according to the indications of your problem. If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

If you use more BETADINE® Vaginal Douche than you should

In the event of accidental or deliberate ingestion of large quantities of **BETADINE® Vaginal Douche**, contact immediately your doctor or nearest hospital.

Symptoms:

Metallic taste in the mouth, increased salivation, burning or pain in the throat or mouth, irritation and swelling in the eyes, breathing difficulties due to pulmonary oedema, skin reactions, gastrointestinal upset and diarrhoea. Metabolic acidosis, hypernatraemia and renal impairment may occur.

Systemic toxicity may result in renal impairment (including anuria), tachycardia, hypotension, circulatory failure, oedema of glottis resulting in asphyxia, or pulmonary oedema, seizures, fever and metabolic acidosis. Hyperthyroidism or hypothyroidism may also develop.

Therapy:

Symptomatic and supportive treatment should be provided, with special attention to electrolyte balance and renal and thyroid function.

For severe hypotension, intravenous fluid should be administered; vasopressors should be added if necessary.

Endotracheal intubation may be required if caustic injury to the upper airway results in significant swelling and oedema.

Vomiting should not be induced. Patient should be maintained in a position to keep the airways open and prevent aspiration (in case of vomiting).

If the patient is not vomiting and can tolerate oral feeding, then ingestion of starchy food (e.g. potato, flour, starch, bread) may help convert iodine to less toxic iodide. If no signs of bowel perforation are present, irrigation of the stomach with starch solution via nasogastric tube may be utilized (gastric effluent will turn dark blue-purple and the colour can be used as a guide in determining when lavage can be terminated).

Haemodialysis effectively clears iodine and should be employed in severe cases of iodine poisoning particularly if renal failure is present. Continuous venovenous haemodiafiltration is less effective than haemodialysis.

In case of thyroid dysfunction, treatment with povidone-iodine should be discontinued.

4. Possible side effects:

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

Povidone-iodine use could lead to transient skin discolouration at the application site.

The course of treatment is usually free of any discomfort, but if irritation, redness or swelling develop, discontinue use and consult your doctor.

The application of Povidone-iodine to large wounds or severe burns may produce systemic adverse effects such as metabolic acidosis, hypernatraemia and impairment of renal function. Iodine is absorbed from the vagina and following prolonged use thyroid dysfunction may develop.

In single cases acute generalised allergic reactions with drop in blood pressure and/or shortness of breath (anaphylactic reactions) have been reported.

Should you experienced any of the above side effects or any other unusual effects, stop using the medicine and consult your doctor or pharmacist at once.

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 to:

ADR Reporting Website:

www.medicinesauthority.gov.mt/adrportal

By reporting side effects, you can help provide more information on the safety of this medicine

5. How to store BETADINE® Vaginal Douche

- Keep this medicine out of the sight and reach of children
- Store this product at or below 25°C, in the packaging that it comes in.
- Do not use this product after the expiry date shown on the pack carton after the EXP. The expiry date refers to the last day of that month.
- 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 BETADINE® Vaginal Douche contains

- The active substance is Povidone-Iodine Ph Eur 10%w/v.
- The other excipients are Nonoxinol 9, Fleurome Bouquet 477, Purified Water.

What BETADINE® Vaginal Douche looks like and contents of the pack

BETADINE® Vaginal Douche is an intra-vaginal dark-brown solution filled in a turquoise polyethylene container containing 125ml, 250ml and 500ml with a transparent polyethylene insert and white high density polyethylene cap. **BETADINE® Vaginal Douche** is also available as **BETADINE® Vaginal Douche Kit**, which contains an empty squeeze bottle and a vaginal applicator. The products are enclosed in printed cartons.

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

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