NAME OF PRODUCT

POVIDONE-IODINE (BETADINE®) 10% (100mg/mL) Vaginal Douche

Read this leaflet carefully before you start using this medicine.

- 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. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- If any of the side effects become serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

DESCRIPTION OF PRODUCT

POVIDONE-IODINE (BETADINE®) 10% (100mg/mL) Vaginal Douche is available in 120 mL bottle together with an applicator and 120 mL refill bottle.

1. WHAT IS BETADINE® 10% (100mg/mL) VAGINAL DOUCHE?

POVIDONE-IODINE (BETADINE®) 10% (100mg/mL) Vaginal Douche contains Povidone-Iodine 10% (100mg/mL) w/v as the active ingredient.

Povidone-Iodine is an antiseptic. Antiseptics are chemicals that kill or prevent the growth of micro-organisms (bacteria, fungi and viruses).

It does not stain the skin and can be washed off if spilt on to clothing.

2. STRENGTH OF THE MEDICINE

Each mL contains 100 mg POVIDONE-IODINE (BETADINE®) equivalent to 10 mg available iodine

3. WHAT IS THIS MEDICINE USED FOR?

POVIDONE-IODINE (BETADINE®) 10% (100mg/mL) Vaginal Douche is used as a vaginal cleanser for the treatment of vaginitis due to candidal, trichomonal, bacterial non-specific or mixed infections and for pre-operative disinfectant of the vagina.

4. HOW MUCH AND HOW OFTEN SHOULD YOU USE THIS MEDICINE?

Use POVIDONE-IODINE (BETADINE®) 10% (100mg/mL) Vaginal Douche as prescribed by your doctor or follow the instructions below:
For the treatment of vaginitis use once daily in the morning for 14 days including days of menstrual cycle.
- For personal hygiene, use twice a week.

**HOW TO DOUCHE?**

**Therapeutic Douche:**

1. Pour POVIDONE-IODINE (BETADINE®) 10% (100mg/mL) Vaginal Douche into the squeezable syringe bottle up to the FIRST-FILL-LINE (Figure A) (15 mL). Add lukewarm water up to the WATER-FILL-LINE (Figure B) approximately 400 mL. Attach nozzle to douche bottle and shake gently to mix, holding bottle straight until ready to use.

![First Fill Line](Fig. A) ![Water Fill Line](Fig. B)

Note:
Whatever douche or douching apparatus you use, be sure to let the first few drops run out before you insert the nozzle, to prevent any possible air bubble from entering. This applies to all douches.

2. Gently insert nozzle about three inches into the vagina. Hold douche bottle so as to provide proper flow of contents.

![Insert Nozzle](Fig. C)

3. Squeeze douche bottle gently on both sides. Use a sustained even pressure so solution can flow in gently. Do not release pressure and continue squeezing until most of the solution is used up. Discard the small amount left in the douche bottle.

4. Make a second identical dilution and repeat procedure.
5. Rinse out the douche and nozzle and let them drain dry.

**Routine Cleansing Douche:**

Pour POVIDONE-IODINE (BETADINE®) 10% (100mg/mL) Vaginal Douche squeezable douche bottle up to ½ of the FIRST-FILL-LINE (Figure A).
Add lukewarm water up to the WATER-FILL-LINE (Figure B) approximately 400mL. Attach nozzle to douche bottle and shake gently to mix, holding bottle straight until ready to use. Then follow Steps 2 – 5 of Therapeutic Douche.

WHERE TO DOUCHE?

The multiple creases and folds of the vaginal canal make it necessary to wash the walls of the vaginal canal thoroughly with douche solution. Therefore, the most effective results are obtained by reclining in the bath tub with knees drawn up permitting more effective irrigation. (You may take the chill off the tub by running in some warm water and then draining it out.)

If you prefer douche while sitting back on the toilet or douche in the shower. It helps to be relaxed wherever you douche.

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

5. WHEN SHOULD YOU NOT USE THIS MEDICINE?

POVIDONE-IODINE (BETADINE®) 10% (100mg/mL) Vaginal Douche should not be used:

- If you are allergic to iodine or povidone
- If you have an overactive thyroid gland (hyperthyroidism) or any thyroid diseases
- Before and after a specific medical treatment involving the use of radioactive iodine

If you feel you have experienced an allergic reaction, stop using this medicine and inform your doctor or pharmacist immediately.

6. UNDESIRABLE EFFECTS / SIDE EFFECTS

All medicines can have side effects. Sometimes they are serious, most of the time they are not. You may need medical attention if you get some of the side effects.

The side effects listed below may not include all of the side effects reported. For more information about any other possible risks associated with this medicine, please consult your doctor or pharmacist.
Please note that the side effects related to the use of POVIDONE-IODINE (BETADINE®) 10% (100mg/mL) Vaginal Douche occurs rarely and do not be alarmed by the following lists of side effects.

You may not experience any of them during normal use. Rarely, hypersensitive/allergic skin reaction may occur which can appear in the form of:

- Itchiness,
- Redness
- Small blisters

Very rarely, acute generalized allergic reactions have been reported with

- Drop in blood pressure
- Difficulty in breathing
- Swelling of the skin and mucosa

If you notice any side effects, please tell your doctor or pharmacist.

The long term use of the product, not in accordance with the usage instructions mentioned under section 4, may lead to possible absorption of iodine into the body. This may lead to

- Overactive thyroid gland function if you have a history of thyroid problems, rapid heartbeat (tachycardia) and restlessness
- Imbalance of electrolytes
- Abnormal blood concentration (osmolarity)
- Abnormal kidney function (renal impairment)

7. WHAT OTHER MEDICINE OR FOOD SHOULD BE AVOIDED WHILST USING THIS MEDICINE?

Do not apply other medications to the same affected areas you treat with POVIDONE-IODINE (BETADINE®) 10% (100mg/mL) Vaginal Douche, unless your doctor has told you so.

It is not likely that other drugs you take orally or inject will have an effect on externally applied POVIDONE-IODINE (BETADINE®) 10% (100mg/mL) Vaginal Douche.

The concomitant use of other externally applied wound healing medicines /preparations may alter the effect of POVIDONE-IODINE (BETADINE®) 10% (100mg/mL) Vaginal Douche or both. Products containing mercury, silver, hydrogen peroxide, and taurolidine may interact with Povidone-Iodine and should not be used concomitantly.

Do not start a new treatment medication without telling your doctor.

For more information about any other possible risks associated with this medicine, please consult your doctor or pharmacist.
8. WHAT SHOULD YOU DO IF YOU MISS A DOSE?

Follow the usage instructions mentioned in section 4. If you miss a treatment use it as soon as you remember. For more information please consult your doctor or pharmacist.

9. HOW SHOULD YOU KEEP THIS MEDICINE?

Do not use this medicine after the expiry date indicated on the bottle and carton.

Store at temperatures not exceeding 30°C.

10. SIGNS & SYMPTOMS OF OVERDOSE

In an unlikely event, If you should experience any of the following symptoms: stomach pain, unable to pass urine, loss of appetite, weakness, nausea and vomiting, coughing up blood, excessive sweating, anxiety and pale skin, immediately consult your doctor.

11. WHAT TO DO WHEN YOU HAVE USED MORE THAN THE RECOMMENDED DOSAGE?

Please consult your doctor or pharmacist.

12. CARE THAT SHOULD BE TAKEN WHEN USING THIS MEDICINE?

Keep out of the reach and sight of children.

It is a spermicidal and not recommended when conception is desired.

This medication is intended FOR EXTERNAL USE ONLY and not for use on extensive body areas. If symptoms continue, discontinue use and consult a doctor.

Do not heat the medicine prior to use.

This medication should not be used over a long period of time.

Avoid getting this medication in your eyes.

Pregnancy and Lactation

Always inform your doctor or pharmacist if you are pregnant or planning a pregnancy, before using any medicine.

This medicine is not recommended for use in pregnancy or breastfeeding. Seek medical advice from your doctor or pharmacist.

13. WHEN SHOULD YOU CONSULT YOUR DOCTOR?

In case of allergic symptoms, stop treatment and consult your doctor.
Call your doctor if your symptoms do not improve or if they get worse. Also call your doctor if your symptoms had cleared up but reappeared again.

14. NAME/LOGO OF MANUFACTURER/IMPORTER/MARKETING AUTHORIZATION HOLDER

The medicine is manufactured by Pascual Laboratories Inc., Km. 31 MacArthur Highway, Balagtas, Bulacan for Mundipharma Distribution GmbH (Philippine Branch), Unit 1706-1709 Robinsons Equitable Tower, #4 ADB Ave. corner Poveda St., Ortigas Center, Pasig City. Under license by: Mundipharma B.V. / The Netherlands

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