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

This medicine is dispensed without prescription of doctor
The format of this leaflet was determined by the Ministry of Health
and its content was checked and approved by it in 08/2014

POLYSEPT VAGINAL DOUCHE

Composition:

Povidone Iodine 10%

For the list of inactive ingredients: See section 6 "Further information"

Read the entire leaflet careful before you start using this medicine. This leaflet contains concise information about this medicine. If you have further questions, refer to the physician or pharmacist.

This medicine is dispended without prescription of doctor. This medicine is intended for administration to adult. Take the medicine correctly.

Consult a pharmacist if you need further information. Consult a doctor if symptoms do not pass within 5 days despite use this medicine.

1. what is this medicine intended for?

This medicine is intended to antiseptic rinse of the vagina.

Therapeutic action: lodine is an antiseptic

2. Before use this medicine:

Do not take this medicine:

- Do not use this medicine if you are sensitive to lodine or to any of its ingredients.
- Do not use for vaginal rinse in children.
- Do not use if you are pregnant or breast-feeding

Special warning regarding use of the medicine:

If you are sensitive to any type of food or medicine inform your doctor before starting treatment with

inform your doctor before starting treatment with this medicine.Do not use this medicine frequently or for a long

period of time without consulting a doctor.

Do not use this medicine without consulting a

- doctor before commencing treatment:

 If you are suffering or have suffered in the past from impaired function of the thyroid gland.
- Vaginal douche- do not use during pregnancy and breast feeding without consulting a doctor for fear of damage to the fetus thyroid gland.
- if you have pelvic inflammatory disease, or a history
 forwally transmitted disease.

of sexually transmitted diseases

If you are taking or if you have just finished treatment with another medicine including medicine over the counter, dietary supplement or vitamins, inform the doctor or pharmacist. It is especially important to inform the doctor or pharmacist if you are taking a medicine from the following groups or if you have just finished treatment with the medicine:

• Lithium

Pregnancy and breast-feeding:

If you become pregnant while taking this medicine, consult your doctor the benefits and risks of using polysept vaginal douche during pregnancy. If you are pregnant, consult your doctor before starting use of this medicine.

- · Do not use this medicine of you are breastfeeding.
- Do not use polysept vaginal douche sooner than 6 hours after intercourse if you were using a vaginal spermicide for contraception.
- Polysept vaginal douche is not a contraceptive agent It will not prevent pregnancy.

How should you use this medicine?If you are uncertain as to how to use this medicine,OutputDescription<

consult your doctor or your pharmacist.

Recommended dosage unless otherwise

prescribed by your doctor:

For vaginal douche:

mix 1 tablespoon (15 ml) of Polysept with 1 liter of lukewarm water. Douche twice a week.

If there is no change in your condition after 5 days, consult a doctor.

Do not use for vaginal rinse in children.

Polysept vaginal douche does not stain the skin and cotton material.

Do not exceed the recommended dose.

Do not swallow! This medicine is intended for external use only.

If you have accidentally taken an overdose, or if a child has accidentally swallowed the medicine, refer immediately to a doctor or to a hospital emergency room and bring the medicine package with you.

If you forget to take this medicine, take the dose as soon as you remember, but never take a double dose at the same time. Take your next dose at the usual time and consult a doctor or pharmacist.

Do not take medicines in the dark! Check the label and the dose <u>each time</u> you take your medicine. Wear glasses if you need them.

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

4. Side Effects:

Like all medicines, **Polysept vaginal douche** use can cause side effects, although not everybody gets them. Do not be alarmed by this list of possible events. You may not have any of them.

- If you experience a skin rash, hives, or itching, or any other unusual reaction after using this product, discontinue use and contact your doctor as soon as possible
- If symptoms of vaginal itching and irritation persist for more than 5 days, or if redness, swelling, or pain develops, stop use and contact your doctor.
- Seek medical attention immediately if you are experience one of these following severe side effects: Severe allergic reactions (severe rash; hives; itching; difficulty breathing; tightness in the chest; swelling of the mouth, face, lips, or tongue); chills; excessive vaginal dryness; fever; severe stomach pain; unusual vaginal discharge; vaginal pain, soreness, swelling, redness, or irritation.

If you get a side effect, if any of the side effects gets worse, or if you get any side effects not mentioned in this leaflet, consult immediately your doctor.

5. How to store this medicine?

Avoid poisoning! This medicine and any other medicine should be kept in a closed place out of reach of children and/or infants in order to avoid poisoning. Do not induce vomiting without an explicit instruction from the doctor.

- from the doctor.

 Do not use the medicine after the expiry date (exp. date) appearing on the package. The expiry date refers to the last day of that month.
- Store in a dry place, at a temperature below 25°C.
 This medicine can be used up to 4 weeks from first opening.

6. Further information:

In addition of active ingredient (substance) this medicine contains also:

Inactive ingredients: Purified Water, Disodium Hydrogen Phosphate, Citric Acid Anhydrous, Polyethylene Glycol, Poloxamer - 407.

What does the medicine look like and what is the content of the package?

Brown suspension packaged in bottle

Holder and manufacture: Rekah Pharmaceutical Industry Ltd. 30 Hamelacha St. Holon, Israel.

This leaflet was checked and approved in August 2014 **License number:** 140-19-31669-00

מק"ט: 5PO1010A 08/14