



POLYDINE[®]

OINTMENT

Patient package insert in accordance with the Pharmacists' Regulations (Preparations) 1986.

No doctor's prescription is needed.

The format of this bulletin was determined by the Ministry of Health who has reviewed and approved its content.

Active Ingredient: Povidone Iodine 10%

Inactive Ingredients and Allergens in this medicine: See paragraph 6 "Additional information".

Read this leaflet carefully in its entirety before using this medicine. This leaflet contains essential information about the medicine. If you have additional questions, consult your doctor or a pharmacist.

You must use this medicine in a proper manner:
Consult your pharmacist if you need additional information.

1. Therapeutic Activity:

- Antiseptic preparation. Intended for wound disinfection, superficial burns and antiseptics of infected skin conditions.
- Therapeutic Group: Antiseptic substances (disinfectants).

2. Before using the medicine:

Do not use the medicine if:

You are sensitive (allergic) to one of the ingredients of the medicine or to Iodine.

If you are sensitive to a particular food or medicine, you should report this fact to your doctor before commencing treatment with this medicine.

Special warnings concerning the use of the medicine:

- If you are taking another drug concomitantly or if you have just finished treatment with another medicine, including non prescription medicines or food supplements, inform the doctor or the pharmacist in order to prevent hazards or lack of efficacy arising from drug interactions.
- Avoid using on large areas of the skin.
- In case of a deep wound or a serious burn and if the wound condition does not improve or gets worse, consult your doctor.
- Do not use this medicine frequently or for a long period of time without consulting your doctor.
- If you suffer/ed from a malfunction of the Thyroid gland, do not use the medicine before consulting a doctor.
- Pregnancy and breastfeeding: If you are pregnant or breastfeeding, consult a doctor or a pharmacist before you begin using the medicine.

3. How to use the medicine?

Consult your doctor or pharmacist if you have any doubts.

Attention: do not swallow! This medicine is intended for external use only.

Directions for use:

- Apply to the wound or treated area 2-4 times daily.
- The ointment can be applied to a gauze pad and held in place with a bandaid.
- If there is no improvement in your condition within a week you should consult your doctor.
- Stains on the skin or on cotton fabric will be cleaned by rinsing in water.

Do not take this medicine in the dark! Check the label and dose **each time** you use your medicine. Wear glasses if you need them.

4. Side Effects:

- Like in other drugs, using Polydine ointment may cause some side effects for some of the users. No need to be alarmed while reading the side effects list. You probably will not suffer from any of them.
- In addition to the desirable impact of the medicine, there might be some side effects, like an irritation.
- In rare cases of prolonged rash, irritation or swelling, stop treatment immediately and consult your doctor.
- Children and infants: Parents must inform the doctor on each side effect.
- In any case you feel any side effects that are not mentioned in this leaflet or any change in your general health, consult your doctor immediately.

5. How to store the medicine?

- **Avoid Poisoning!** This medicine like all other medicines, must be stored in a safe place and out of the reach of children and/or infants, to avoid poisoning. If a child has accidentally swallowed the medicine, proceed immediately to a hospital emergency room and bring the package of the medicine with you.

Do not induce vomiting unless explicitly instructed to do so by a doctor!

- Shelf life after opening is up to 36 months. Do not use the medicine after the expiry date printed on the package. The expiry date is always the last day of that month.
- Do not store over 25°C.
- Always keep in the original package.

6. Additional information

- In addition to the active ingredient, the medicine also contains: PEG 400, PEG 4000, Purified Water, Trisodium Phosphate.
- How does the medicine look like and what are the contents of the package?

A dark brown ointment, a typical Iodine smell.

- Package sizes: 15 and 50 gram tubes, 250 gram jar.
- The registration owner: Fischer Pharmaceutical Labs. (1975) Ltd. P.O.B. 39071, Tel-Aviv 61390.
- Manufacturer: Ben-Shimon Floris Ltd., Misgav Industrial Park, Misgav 20174.
- This bulletin was reviewed and approved by the Ministry of Health on: 11/2014.
- The medicine's license number in the state medicine registry at the Ministry of Health is 116.74.23415