

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

This medicine is dispensed without a doctor's prescription.

## **POLYDINE®**

### **Solution**

**The active ingredient and its concentration:**

**Povidone Iodine 10%. ( Equivalent to 1% Iodine)**

**For the list of inactive and allergenic ingredients in the preparation, see Section 6 "Further Information".**

**Read the leaflet carefully in its entirety before using the medicine.** This leaflet contains concise information about the medicine. If you have any further questions, refer to your doctor or pharmacist.

You must use this medicine correctly. Consult your pharmacist if you need additional information.

#### **1. WHAT IS THIS MEDICINE INTENDED FOR?**

- **This medicine is intended for first aid treatment of wounds, scratches and mild burns, for antiseptic treatment of wounds and mild burns, and for the treatment of skin infections.**
- **Therapeutic group:** Antiseptics (disinfectants).

#### **2. BEFORE USING THIS MEDICINE:**

**Do not use this medicine if:**

Do not use if you are sensitive (allergic) to any of the preparation's ingredients or to iodine.
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If you are sensitive to any food or medicine, inform the doctor before using the medicine.

**Special warnings concerning the use of the medicine:**

- **If you are taking or have recently taken other medicines, including non prescription medicines and nutritional supplements, inform the physician or pharmacist** in order to avoid risks or inefficacy resulting from drug interactions.
- Avoid using on large areas of the skin. A doctor should be consulted before treating deep wounds.
- Do not start treatment without first consulting a doctor if you suffer, or have suffered in the past, from impaired thyroid gland function.
- **Pregnancy and breastfeeding:** If you are pregnant or breastfeeding, consult a doctor or pharmacist before using the medicine.

#### **3. HOW SHOULD YOU USE THIS MEDICINE?**

Consult the doctor or pharmacist if you are uncertain.

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

**How to use the product – general directions:**

- Polydine Solution can be dripped directly onto the skin and

wound, and left to dry on the skin (a protective layer will be formed). It can also be applied using a gauze pad: dip the pad in the solution, place it on the wound, and cover it with a bandage.

- First aid: To treat a wound – apply Polydine 2-4 times daily until the wound heals. For skin infections, apply Polydine Solution as above until complete healing or according to the doctor's instructions.
- If there is no improvement in your condition within a week, consult your doctor.
- Stains on your body or on cotton fabric can be cleaned by rinsing in water.

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

#### **4. SIDE EFFECTS:**

- As with any medicine, using **Polydine Solution** can cause side effects in some users. Do not be alarmed when reading the list of side effects. You may not suffer from any of them.
- In addition to the desired effect of the medicine, side effects, such as persistent rash, irritation or swelling, may occur during its use.
- **If one of the side effects worsens, or if you suffer from a side effect not mentioned in this leaflet, you must consult your doctor.**

#### **Reporting of side effects:**

Side effects can be reported to the Ministry of Health by clicking on the link "Report Side Effects of Drug Treatment" found on the Ministry of Health homepage ([www.health.gov.il](http://www.health.gov.il)) that directs you to the online form for reporting side effects, or by entering the link:

<https://sideeffects.health.gov.il/>

#### **5. HOW SHOULD THE MEDICINE BE STORED?**

- **Avoid poisoning!** This medicine, and all other medicines, must be kept in a safe place out of the reach and sight 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 the doctor.

- May be used for 36 months after the bottle is first opened. Do not use this medicine after the expiry date (exp. date) that appears on the packaging. The expiry date refers to the last day of that month.
- Do not store at a temperature higher than 25°C.
- Store in the original packaging.

#### **6. FURTHER INFORMATION**

- In addition to the active ingredient, this medicine also contains: **PEG 400, PEG 4000, Purified Water, Trisodium Phosphate**
- What does the medicine look like and what are the contents of the package? Clear dark brown liquid. Content: 20 ml, 100 ml, 1000 ml.
- Registration holder: Fischer Pharmaceutical Labs (1975) Ltd., 9 Bar Yohai Street, Bnei Brak 5155309, or POB 39071, Tel Aviv 6139001.
- Manufacturer's name and address: Ben Shimon Floris Ltd., Misgav Industrial Park, Misgav Mobile Post 20174.
- The format of this leaflet was determined by the Ministry of Health, and its content was checked and approved by the Ministry of Health in November 2014. It was updated in accordance with Ministry of Health guidelines in December 2023.
- Registration number of the medicine in the National Drug Registry of the Ministry of Health: 1319623410