

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

Non-prescription medicine

Iodine Tincture

Tincture

FLORIS

Composition: Active substances and their concentration:

Iodine 2.5%, Potassium Iodide 2.5%

For the list of the inactive substances: **See Section 6 "Additional information". Read the insert carefully to the end before using the medication.** This insert contains abridged information on the medicine. If you have further questions, consult your doctor or pharmacist. Use the preparation correctly. Consult your pharmacist if you require additional information.

1. What the medicine is used for ?

This medicine is indicated for local disinfection.

Therapeutic Group - Antiseptic preparations (disinfectants)

2. Before using the medicine

ⓧ Do not use the medicine: If you are sensitive (allergic) to the active substance Iodine or to any of the additional ingredients contained in the medicine. For the list of the inactive substances - see Section 6 "Additional information"

ⓧ Special warnings concerning use of the medicine:

Do not light a cigarette or expose yourself to an open flame until the preparation is fully dried.

- Consult your physician before treating deep wounds/severe burns.
- If you are sensitive to any food or medicine, inform your physician before using this medicine.
- Do not use this medicine frequently, or for a long period, without consulting a physician.
- Do not use this medicine on large areas of the skin.

ⓧ Before treatment with Iodine Tincture, tell your doctor if you are suffering or have suffered in the past from thyroid dysfunction

ⓧ If you are taking, or recently took, other medicines, including over the counter medicines and dietary supplements, inform your doctor or pharmacist.

ⓧ Pregnancy and Breast-feeding: If you are pregnant or if you are breast-feeding, consult your doctor before using the medicine.

ⓧ Important information about some of the ingredients of the medicine: The iodine substance in the medication might stain clothing. The medication contains alcohol, a flammable substance.

3. How to use the medicine?

Ask your doctor or pharmacist if you are not sure how to use it.

Generally recommended dosage: Apply the solution to the affected area. Do not apply to a large area of wounded skin. Do not bandage the wounded area hermetically. Avoid contact with the eyes - in case of contact, rinse thoroughly with water. In the event of local irritation or inflammation or rash, consult your doctor. Do not exceed the recommended dosage. Do not swallow. For external use only. If you have taken an overdose or if a child has accidentally swallowed the medicine, go immediately to a doctor or a hospital emergency room and bring the medicine package with you.

Do not take medicines in the dark! Check the label and the dose each time you take your medicine. Wear glasses if you need them. If you have further questions concerning use of the medicine refer to your doctor or pharmacist.

4. Side Effects:

As for any medicine, the use of Iodine Tincture may cause side effects in some users. Do not be alarmed by the list of side effects. You will probably not suffer from any of them.

Stop treatment and refer to your doctor:

- In the event of local itching, rash or inflammation (that did not exist before use of this preparation), (rare). Consult your doctor immediately if you experience a side effect not indicated in this insert or if there is a change in your general feeling.

Reporting Side Effects: You can report side effects to the Ministry of Health through the online form for reporting side

effects that you will find on the homepage of the Ministry of Health. website: www.health.gov.il

or by entry to the link

<https://forms.gov.il/globaldata/getsequence/getsequence.aspx?formType=AdversEffectMedic@moh.gov.il>

5. How to store the medicine?

• **Avoid poisoning!** This medicine, and all other medicine, must be stored in a safe place out of the reach of children and/or infants, in order to avoid poisoning.

Do not induce vomiting unless explicitly instructed to do so by the doctor.

• Do not use the medicine after the expiry date appearing on the package.

The expiry date refers to the last day of that month.

- Store in a cool place, below 25°C.
- Close tightly to prevent entry of air and damp.
- Store in the original package.
- You can use the product after first opening the bottle for 3 years.

6. Additional information

In addition to the active substances the medicine

also contains: Alcohol 95%, Purified water
Appearance of the medicine and contents of the package: Brown solution Contents: 10 ml.
Manufacturer and Reg.

Owner: Ben-Shimon Floris Ltd.,
Misgav Industrial Park, D.N. Misgav 2017400.
This leaflet was inspected and approved by the Ministry of Health on: August 6, 2015.
Registration No. of the medicine in the National Drug Register of the Ministry of Health:
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