

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

The medicine can be sold without a doctor's prescription

# Inotyol Ointment

Each 100 grams of ointment contains:  
Zinc oxide 14.763 grams,  
Titanium dioxide 5.905 grams,  
Ichthammol 1.474 grams,  
Hamamelis extract 0.984 gram,  
Siam benzoin 0.1 gram.

Inactive and allergenic ingredients in the preparation – see section 2 “Important information about some of the ingredients of the medicine” and section 6 “Further information” in the leaflet.

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

Use the preparation according to the instructions in the dosage section of this leaflet. Consult the pharmacist if you need further information. Refer to the doctor if the symptoms of the disease worsen or are not improving after a few days.

## 1. WHAT IS THE MEDICINE INTENDED FOR?

For local treatment of eczema, feet ulcers, mild burns and skin irritations such as: skin redness in infants (diaper rash), cold sores on the skin.

**Therapeutic group** – Ointment for treatment of skin irritation, sores and ulcers.

## 2. BEFORE USING THE MEDICINE

### Do not use the medicine if:

- you are hypersensitive (allergic) to the active ingredients (see above) or to any of the additional ingredients contained in the medicine (see section 2 “Important information about some of the ingredients of the medicine” and section 6 “Further information”).
- you are suffering from skin inflammation with discharge or infection.
- your child suffered in the past from seizures, due to fever or other reasons (since the preparation contains terpene derivatives).

If you are uncertain, consult with a doctor or pharmacist.

### Special warnings regarding the use of the medicine

- Do not apply more than the recommended dosage (see section 3 “How to use the medicine?”).
- Do not apply on an extensive area of the skin.
- Follow the recommended instructions for use regarding frequency and duration of use.

### Before treatment with Inotyol, tell the doctor if:

- You recently suffered or suffered in the past from epilepsy.

### Drug interactions:

**If you are taking, or have recently taken, other medicines, including non-prescription medicines and nutritional supplements, tell the doctor or pharmacist.**

### Pregnancy and breastfeeding

If you are pregnant or breastfeeding – do not use Inotyol.

If you are pregnant, think you may be pregnant or are planning to become pregnant, consult the doctor or pharmacist before using Inotyol.

### Important information about some of the ingredients of the medicine

Inotyol contains:

- alcohol (ethanol) – each 50 gram tube contains 0.15 gram alcohol, which may cause a burning sensation in damaged skin.

In newborns (who were born premature or at term), high concentrations of ethanol may cause severe localized reactions and systemic toxicity due to significant absorption through the skin that has not fully developed (especially if it is covered).

- lanolin (wool fat) – which may cause localized skin reactions (e.g., contact dermatitis).
- terpene derivatives – which may (on use of high dosages) cause neurological events, such as seizures in infants and children.
- limonene and linalool (components of lavender oil used as a fragrance) – which may cause allergic reactions.

## 3. HOW TO USE THE MEDICINE?

Check with the doctor or pharmacist if you are uncertain about the dosage and treatment regimen of the preparation.

The recommended dosage is usually: Apply a thick layer of ointment on the skin, two to three times a day.

Before using the ointment, make sure that the treated area is clean, dry and not infected. **Do not exceed the recommended dose.**

If there is no improvement in your condition within a few days, refer to the doctor.

### Instructions for use

For external use only. Do not swallow.

**If you have accidentally used a higher dosage**, there is risk of neurological events, such as seizures in infants and children, and possibly also restlessness and confusion in the elderly.

If you accidentally applied an overdose of the ointment, or if a child or someone else has accidentally swallowed the medicine, refer immediately to a doctor or proceed to hospital emergency room and bring the package of the product with you.

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

**If you have further questions regarding use of the medicine, consult the doctor or pharmacist.**

## 4. SIDE EFFECTS

As with any medicine, use of Inotyol may 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 particular, there is risk of allergy to one of the ingredients of the product (lanolin – wool fat, benzoin and ect.,). The following may occur due to the presence of terpene derivatives as inactive ingredients in the preparation and when the recommended dosages are not adhered to:

- risk of seizures in infants and children.
- possibility of restlessness or confusion in elderly patients.

**If a side effect occurs, if one of the side effects worsens, or if you suffer from a side effect not mentioned in the leaflet, consult with the doctor.**

### Reporting 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>

Additionally, you can report to Padagis via the following address:

[Padagis.co.il](http://Padagis.co.il)

## 5. HOW SHOULD THE MEDICINE BE STORED?

- Avoid poisoning! This medicine and any other medicine should be kept in a safe place out of the reach and sight of children and/or infants 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 (exp. date) that appears on the tube and carton. The expiry date refers to the last day of that month.
- Store below 25°C.
- After first opening, can be used for 6 months, but no later than the expiry date.
- Do not discard any medicine in wastewater or the household waste. Consult the pharmacist how to dispose of a medicine after you no longer use it. These measures will help protect the environment.

## 6. FURTHER INFORMATION

- **In addition to the active ingredients, the medicine also contains:**

Wool fat, light liquid paraffin, white soft paraffin, purified water, ethanol anhydrous or ethanol 96%, lavender oil.

- **What the medicine looks like and the contents of the package:** Inotyol Ointment is a beige ointment with a characteristic fragrance, packaged in a tube that contains 50 grams.

- **Registration holder and address:** Padagis Israel Agencies Ltd., 1 Rakefet St., Shoham.

- **Manufacturer and address:** Laboratoires Uργο Healthcare, Chenove, France.

- Revised in December 2023 according to MOH guidelines.

- **Registration number of the medicine in the National Drug Registry of the Ministry of Health:** 022.26.21121.