

Patient Package Insert in Accordance with the Pharmacists' Regulations (Preparations) - 1986

This product can be sold without a doctor's prescription

Inotyl Ointment

Each 100 grams (g) of ointment contain:

Zinc oxide 14.763 g.

Titanium dioxide 5.905 g.

Ichthammol 1.474 g.

Hamamelis extract 0.984 g.

Siam benzoin 0.1 g.

Inactive ingredients and allergens in the product - see section 2 "Important information about some of the ingredients of this product" and section 6 in the leaflet.

Read this entire leaflet carefully before you start using this product. This leaflet contains concise information about the product. If you have any further questions, ask the doctor or pharmacist.

Use this product according to the instructions in the dosage section of this leaflet. Consult the pharmacist if you need additional information. Refer to the doctor if the symptoms of the illness worsen or do not improve after a few days.

1. What is the product intended for?

For local treatment of eczema, foot ulcers, mild burns and skin irritations such as: skin redness in infants (diaper rash), chilblains.

Therapeutic group – ointment for treatment of skin irritations, sores and skin ulcers.

2. Before using the product

Do not use the product if:

- you are hypersensitive (allergic) to the active ingredients (see above) or to any of the other ingredients this product contains (see section 2 "Important information about some of the ingredients of this product" and section 6 "Additional information").
- you suffer from dermatitis accompanied by secretions or infection.
- your child has suffered in the past from convulsions, related to fever or other causes (as the product contains terpene derivatives).

Special warnings regarding the use of this product

- Do not apply a higher dosage than recommended (see section 3 "How to use this product").
- Do not apply over a large area of the skin.
- Follow the recommended instructions for frequency and treatment duration.

Before the treatment with Inotyl, tell the doctor if:

- you have recently or in the past suffered from epilepsy.

Drug interactions

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

Pregnancy and breastfeeding

If you are pregnant or breastfeeding – do not use Inotyl. Consult the doctor or pharmacist before using Inotyl if you are pregnant, think you might be pregnant or are planning to become pregnant.

Important information about some of the ingredients of this product

The product contains:

- Lanolin (wool fat) – which may cause a local skin reaction (such as contact dermatitis).
 - Terpene derivatives – which may (at high doses) cause neurological events such as: convulsions in infants and children.
 - Alcohol (ethanol) – each 50 g tube contains 0.15 g of alcohol, which may cause a burning sensation in damaged skin.
- The systemic and skin effects of alcohol are increased in newborns and infants (under two years of age), compared to other children and adults, due to increased absorption through the skin. Consult the doctor or pharmacist before using the product on your baby.
- Limonene and linalool (ingredients found in lavender oil used for fragrance), which may cause allergic reactions in some users.

3. How to use this product

Check with the doctor or pharmacist if you are not sure about the dosage and the treatment regimen.

The usual recommended dosage is:

Application of a thick layer of the ointment on the skin twice or 3 times daily.

Before using the ointment make sure the treated area is clean, dry and free of infection.

Do not exceed the recommended dose.

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

How to use

For external use only. Do not swallow.

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

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

Do not take products in the dark! Check the label and the dose each time you take a product. Wear glasses if you need them.

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

4. Side Effects

As with any product, the use of Inotyl 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 a risk of allergy to one of the product's ingredients (lanolin - wool fat, benzoin, etc.).

Due to the presence of terpene derivatives as inactive ingredients in the product and in the case of non-adherence to the recommended dosages, there may be:

- a risk of convulsions in infants and children.
- a possibility of agitation or confusion in elderly patients.

If a side effect appears, if one of the side effects worsens or if you suffer from a side effect which is not mentioned in this leaflet, consult the doctor.

Reporting of side effects:

Side effects can be reported to the Ministry of Health by clicking on the link "Report adverse effects and problems associated with medications" that can be found on the home page of the Ministry of Health website (www.health.gov.il) directing to the online form of adverse events reporting or by clicking on the following link: <https://sideeffects.health.gov.il>

Additionally, side effects can be reported to Padagis via the following address: Padagis.co.il

5. How to Store the Product

- Avoid poisoning! This product, and any other product, must be stored in a closed 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 product after the expiry date (exp. date) that appears on the tube and package. The expiry date refers to the last day of that month.
- Store below 25°C.
- Can be used for 6 months after first opening, but not later than the expiry date.

6. Additional Information

In addition to the active ingredients, the product also contains:

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

- **What the product looks like and contents of the package:** Inotyl Ointment is a beige ointment, with a characteristic smell, packaged in a tube containing 50 gram.
- **Registration Holder:** Padagis Israel Agencies Ltd., 1 Rakefet St., Shoham 6085000.
- **Manufacturer:** Urgo Healthcare Laboratories, 42 Longvic St, Chenove, France.
- Revised in January 2023 according to MOH guidelines.
- **Drug registration number at the National Drug Registry of the Ministry of Health:** 022.26.21121.

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