SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE MEDICINAL PRODUCT

INOTYOL, ointment

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Ichthammol..... 1.474 g
Zinc oxide..... 14.763 g
Hamamelis..... 0.984 g
Siam benzoin..... 0.100 g
Titanium dioxide..... 5.905 g

For 100 g of ointment.

Notable excipients: wool fat, alcohol (ethanol), lavender essential oil containing limonene, linalool and terpene derivatives.
For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Ointment.

4. CLINICAL PARTICULARS

4.1. Therapeutic indications

Local treatment of eczema, feet ulcers, mild burns and skin irritations.

4.2. Posology and method of administration

Apply as a thick layer 2 or 3 times daily.

4.3. Contraindications

- Known hypersensitivity to any of the ingredients.
- Infected or weeping dermatitis.
- children with a history of convulsions, febrile or otherwise (due to the presence of terpene derivatives as excipients).

4.4. Special warnings and precautions for use

Special warnings

This medicine contains terpene derivatives as excipients, which can lower the seizure threshold. At excessive doses, risk of neurological accidents such as convulsions in infants and children.
Follow the doses and the recommendations for use. In particular, do not apply to a large surface area of the body.
This medicine contains 0.15 g alcohol per 50 g tube. This may cause a burning sensation on damaged skin.

In neonates (premature and full-term), high concentrations of ethanol may cause severe local reactions and systemic toxicity due to significant absorption through the immature skin (particularly under occlusion).
This medicine contains wool fat and may cause local skin reactions (e.g. contact dermatitis).
This medicine contains a fragrance containing limonene and linalool, which may cause allergic reactions. In addition to allergic reactions in sensitised patients, non-sensitised patients may also become sensitised.

Precautions for use

In the event of a history of epilepsy, take into account the presence of terpene derivatives as excipients.

4.5. Interactions with other medicinal products and other forms of interaction

The data available to date do not suggest the existence of any clinically significant interactions.

4.6. Fertility, Pregnancy and breast-feeding

Pregnancy

There are no data available relating to the use of Inotyol in pregnant women. As a precaution, it is preferable to avoid using Inotyol during pregnancy.

Breast-feeding

This medicine should not be used in breast-feeding women due to:

- the absence of kinetic data concerning the excretion of terpene derivatives in breast milk,
- and their potential neurological toxicity in infants.

4.7. Effects on ability to drive and use machines

Not applicable.

4.8. Undesirable effects

Risk of sensitisation to any of the ingredients (wool fat, benzoin, etc.).
Due to the presence of terpene derivatives, as excipients, and in the event of non-compliance with recommended doses:

- risk of convulsions in infants and children,
- possibility of agitation and confusion in the elderly.

Reporting of suspected adverse reactions

Reporting suspected adverse reactions after authorization of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product.
Any suspected adverse events should be reported to the Ministry of Health according to the National Regulation by using an online form at: https://sideeffects.health.gov.il.
Additionally, you can also report to: Padagis.co.il.

4.9. Overdose

In the event of overdose, risk of neurological accidents such as convulsions in infants and children and possibility of agitation and confusion in the elderly.

5. PHARMACOLOGICAL PROPERTIES

5.1. Pharmacodynamic properties

Pharmacotherapeutic group: SKIN PROTECTOR, ATC code: D. Dermatology.

5.2. Pharmacokinetic properties

Not specified.

5.3. Preclinical safety data

Not specified.

6. PHARMACEUTICAL PARTICULARS

6.1. List of excipients

Wool fat, Light liquid paraffin, White soft paraffin, Lavender oil, Ethanol anhydrous **or** Ethanol 96%, purified water.

6.2. Incompatibilities

Not applicable.

6.3. Shelf-life

The expiry date of the product is indicated on the packaging materials.

Shelf life after first opening: 6 months

6.4. Special precautions for storage

Store below 25°C

6.5. Nature and contents of container

50 g sealed aluminium tube, closed with a white polypropylene cap.

6.6. Specials precautions for disposal and handling

No special requirements.

7. REGISTRATION HOLDER

Padagis Israel Agencies Ltd.

1 Rakefet St., Shoham, Israel.

8. MARKETING AUTORISATION NUMBER(S)

02226.21121

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