SUMMARY OF PRODUCT CHARACTERISTICS

1 NAME OF THE MEDICINAL PRODUCT

Undecyl Powder

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each securitainer contains:
Zinc Undecylenate 20%
Undecylenic Acid 2%

For the full list of excipients, see section 6.1

3 PHARMACEUTICAL FORM

White, free flowing powder.

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

Prophylaxis and treatment of mycotic skin infections particularly athlete's foot.

4.2 Posology and method of administration

Route of administration: Dermal administration.

The medicine is not intended for children and infants under 2 years of age.

Treatment
The usual recommended dosage for adults and children above 2 years of age:
Sprinkle twice daily (morning and evening) on the foot and between the toes after washing and drying thoroughly. Additionally, it is recommended to sprinkle the powder inside the socks, before wearing them each day.
Prevention
The usual recommended dosage for adults and children above 2 years of age:
Sprinkle once daily on the foot and between the toes after washing and drying thoroughly.
Additionally, it is recommended to sprinkle the powder inside the socks, before wearing them each day.

Continue to use **Undecyl Powder** for a week after the symptoms of the fungal infection have disappeared.

If the condition worsens, the patient should contact a doctor.

4.3 Contraindications

Hypersensitivity to the active ingredients (Zinc Undecylenate, Undecylenic Acid) or to any of the excipients listed in section 6.1.

4.4 Special warnings and precautions for use

- The medicine should not be swallowed! This medicine is intended for external use only.
- Contact with the eyes and mucous membranes should be avoided.
- Do not apply to broken skin.
- Treatment should be discontinued if irritation is severe.
- The medicine is not effective while applying on the scalp, nails, or mucosal membranes.
- The medicine is not intended for children and infants under 2 years of age, unless recommended and supervised by a doctor.
- Keep all medicines out of the reach of children.

4.5 Interaction with other medicinal products and other forms of interaction

No clinically significant interactions known.

4.6 Pregnancy and lactation

The safety of the medicine during pregnancy and lactation has not been established, but use during these periods is not considered to constitute a hazard.

4.7 Effects on ability to drive and use machines

No or negligible influence.

4.8 Undesirable effects

Hypersensitivity reactions may occur occasionally. Irritation of the skin may rarely occur.

Reporting of suspected adverse reactions
Reporting suspected adverse reactions after authorisation 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 https://sideeffects.health.gov.il

4.9 Overdose

Excessive application to the skin is unlikely to cause untoward effects. In the unlikely event of ingestion of the medicine symptoms of overdose may include nausea, vomiting, diarrhea and general gastrointestinal disturbances.

Treatment
Symptomatic.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

D01AE - Other antifungals for topical use.
Undecylenic Acid and Zinc Undecylenate have anti-fungal and anti-bacterial properties.

5.2 Pharmacokinetic properties

Not applicable.

5.3 Preclinical safety data

There are no preclinical data of relevance to the prescriber which are additional to that already included in other sections of the SPC.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Talc, Colloidal Silicon Dioxide (Aerosil 200), Terpineol.

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:
The medicine can be used for up to 60 days after the securitainer is first opened, and not later than the expiry date that appears on the package.

6.4 Special precautions for storage

Store in a dry place, below 25°C.
Close tightly, to prevent moisture penetration.

6.5 Nature and contents of container

HDPE securitainer with cap (contents 50% HDPE and 50% PE).

Approved package sizes: 30 g, 80 g.
Not all package sizes may be marketed.

6.6 Special precautions for disposal

No special requirements for disposal.

Any unused medicinal product or waste material should be disposed of in accordance with local requirements.

7 MARKETING AUTHORISATION HOLDER AND MANUFCURER

Rekah Pharmaceutical Industry Ltd., 30 Hamelacha St., Holon, 5881904, Israel.

8 MARKETING AUTHORISATION NUMBER(S)

029-47-25330-00

Revised in July 2025 according to MOH guidelines.