PATIENT PACKAGE INSERT IN ACCORDANCE WITH THE PHARMACISTS' REGULATIONS (PREPARATIONS) - 1986
Read this package insert carefully in its entirety before using this medicine. This leaflet has been imprint and checked by health ministry of Israel by it in 03/2011

UNDECYL Ointment

UNDECYL Powder

Composition:

Zinc Undecylenate 21% Undecylenic Acid 2% Inactive ingredients: Zinc Undecylenate 20% Undecylenic Acid 2%

Undecyl ointment: Vaselin, Wool Fat, Water, Mineral Oil, Terpineol, Cetyl Alcohol, Paraffin, Hartolan, Stearyl Alcohol, Cholesterol Undecyl powder: Talc. Colloidal Silicon Dioxide. Terpineol

Therapeutic activity: Antimycotic.

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

When should the preparation not be used?

Do not use this medicine if you are sensitive to any of its ingredients.

Do not take this medicine without consulting a doctor before starting treatment:

If you are suffering, or have suffered in the past, from impaired function of the circulatory system, if you are diabetic, pregnant or breastfeeding.

Warnings: Do not use this medicine frequently, or for a long period, without consulting a doctor. If you are sensitive to any type of food or medicine, inform your doctor before commencing treatment with this medicine, on cracked skin

Drug interactions: If you are taking another drug concomitantly or if you have just finished treatment with another medicine, inform the attending doctor, in order to prevent hazards or lack of efficacy arising from drug interactions. This is especially important for medicines belonging to the following groups: other preparations for the treatment of the skin.

Side effects: In addition to the desired effect of the medicine, adverse reactions may occur during the course of taking this medicine.

Effects that require special attention: If a local irritation or rash develops at the site of treatment (rare): discontinue treatment and refer to the doctor immediately.

Allergic reaction to the preparation such as breathing difficulty, inflammation of the skin or the lips, throat or tongue (rare): discontinue treatment and refer to the doctor immediately.

In the event that you experience side effects not mentioned in this leaflet, or if there is a change in your general health, consult your doctor immediately.

Adverse reactions and drug interactions in children and infants:

Parents must inform the attending doctor about any side effect, as well as any additional medicine being taken by the child.

Recommended dosage unless otherwise prescribed by your doctor: Ointment: Apply between the toes and on the soles of the feet several times daily after washing.

Powder: Sprinkle the powder on the foot and between toes a number of time a day after washing your feet. In addition, it is advisable to dust the powder inside the socks before you wear them. This medicine is not usually intended for administration to children/infants under 2 years of age. If there is no improvement in your condition within 4 weeks, or if your condition worsens, refer to your doctor.

Attention: Do not swallow! This medicine is intended for external use only. Avoid contact with the eyes. This preparation is not effective while applicating in the scalp or nails or mucosal membrane.

How can you contribute to the success of the treatment?

Treatment with this medicine should be continued for another 2 weeks after symptoms have disappeared.

<u>Special instructions:</u> Moisture enhances fungal growth, therefore the affected area should be kept dry. The affected area must be washed before each application of the medicine.

When treating the feet- it is important to wash and dry them thoroughly, especially the area between the toes.

It is best to wear cotton socks and not socks made of wool or synthetic materials. Change the socks several times a day (depending on the amount of sweat). During the appropriate seasons, it is advisable to wear sandals without socks.

Avoid poisoning! This medicine, and all other medicines, must be stored in a safe place out of the reach of children and/or infants, to avoid poisoning. If a child has accidentally swallowed the medicine, proceed immediately to a hospital emergency room and bring the package of the medicine with you. Do not induce vomiting unless explicitly instructed to do so by a doctor! 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.

Storage: Store in a dry place and at a temperature below 25°C.

Close firmly to prevent penetration of air and humidity.

Even if kept in their original container and stored as recommended, medicines may be kept for a limited period only. Please note the expiry date of the medicine! In case of doubt, consult the pharmacist who dispensed the medicine to you. Do not store different medications in the same package.

License number: 137462109000, 029472533000

Manufacturer:

Rekah Pharmaceutical Products Ltd., 30 Hamelacha St., Holon, Israel.