

Patient package insert in accordance with the Pharmacists' Regulations (Preparations) 1986

This medicine is to be dispensed without a doctor's prescription

Sebosel Suspension

Active ingredient and its concentration:

Each 1 ml contains:

Selenium sulfide 25 mg

For a list of the inactive ingredients, please see Section 6.

Read this 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 this medicine correctly. Consult a pharmacist if you need further information. If your condition does not improve or your condition worsens after or during the recommended treatment, consult the doctor.

This medicine is not intended for infants and children. **Do not swallow! This medicine is for external use only.**

1. What is this medicine intended for?

To treat dandruff, seborrheic dermatitis, and tinea versicolor.

Therapeutic group: antifungal.

2. Before using this medicine:

X Do not use this medicine if:

- You are sensitive (allergic) to the active ingredient (selenium sulfide) or to any of the other ingredients that this medicine contains (see Section 6).
- You have open wounds or severe inflammation at the treated site.

⚠ Special warnings regarding the use of the medicine:

- Using this medicine may cause skin irritation, mainly around the genitals and skin folds; wash these areas thoroughly after using this medicine.
- Avoid contact of the medicine with the eyes. If the medicine accidentally gets in the eyes, rinse them immediately with a lot of cold water.
- Make sure you wash your hands and under your fingernails after using this medicine.

- Do not leave the medicine in contact with your hair or skin for longer than the recommended time. This can cause irritation, a burning sensation or blistering. In addition, do not use more often than recommended.
- Before using, remove jewelry made of gold, silver, or other metals, because this medicine may discolor it.
- Thoroughly rinse the medicine out of your hair before dyeing, highlighting, curling, or chemical straightening. Do not use this medicine for two days before or after any of these hair treatments.
- Remove hairpins before use and avoid contact with metallic surfaces.

⚠ Pregnancy and breastfeeding:

Do not use this medicine if you are pregnant, think you may be pregnant or are breastfeeding. If you are pregnant or breastfeeding, consult your doctor or pharmacist before using medicines.

3. How to use this medicine?

Check with your doctor or pharmacist if you are not sure.

The standard dosage and manner of use are usually:

For treating tinea versicolor:

- Apply to the affected area and lather up with a small amount of water.
- Leave the medicine on the skin for approximately 10 minutes.
- Rinse thoroughly.
- Repeat the process once a day for one week.

To treat dandruff and seborrheic dermatitis:

- Massage a small amount (5-10 ml) of the suspension onto a damp scalp.
- Leave on the scalp for 2 to 3 minutes.
- Rinse the scalp thoroughly.
- Repeat the process and rinse thoroughly.
- After treatment, wash your hands thoroughly.
- Perform this treatment twice a week for two weeks, and after that once every one or two weeks or every few weeks. In any case, do not use the medicine more than twice a week.

Do not exceed the recommended dose.

This medicine is not intended for infants and children.

If your condition does not improve or your condition worsens after or during the recommended treatment, consult the doctor. Do not swallow! This medicine is intended for external use only.

Shake the bottle before use.

Avoid contact with the eyes and/or mucous membranes.

If you or a child have accidentally swallowed the medicine, immediately consult a doctor or proceed to a hospital emergency room, and bring the package of the medicine with you. Swallowing Sebosel may cause nausea or vomiting. Do not take medicines in the dark! Check the label and the dose each time you take a medicine. Wear glasses if you need them.

If you have any further questions about using this medicine, consult your doctor or the pharmacist.

4. Side effects:

Like all medicines, using Sebosel may cause side effects in some people. Do not be alarmed by this list of side effects. You may not experience any of them.

- Skin rash or hives
- Irritation or sensitivity of the skin or scalp, sometimes described as a burning sensation.
- Increased hair loss.
- Change in hair color which can be prevented by thoroughly washing the hair after treatment.
- Oily or dry hair or scalp.
- In rare cases there may be blistering, particularly if the medicine is kept in contact with the hair or skin for longer than the recommended duration.

If any side effect gets worse, or if you experience a side effect not mentioned in this leaflet, consult your doctor.

Reporting side effects:

You can report side effects to the Ministry of Health by clicking on the link: "Reporting side effects due to medical treatment" that is found on the homepage of the Ministry of Health website (www.health.gov.il) which refers to the online form for reporting side effects.

5. How to store the medicine?

- Prevent poisoning! To prevent poisoning, keep this, and all other medicines, in a closed place out of reach and sight of children and/or infants. Do not induce vomiting unless explicitly instructed to do so by the doctor.
- Do not use the medicine after the expiry date (exp. date) appearing on the package. The expiry date refers to the last day of that month.
- Store below 25°C.
- Shelf-life after opening: 12 months.

- Do not discard the medicine via wastewater or household waste. Ask the pharmacist how to dispose of medicines you no longer use. These measures will help protect the environment.

6. Additional information:

In addition to the active ingredient, this medicine also contains:

Sodium lauryl ether sulfate, aluminum magnesium silicate, sodium dihydrogen phosphate dehydrate, Cocamide DEA, sodium chloride, citric acid anhydrous, fragrance (I.F.F. #9138) herbal, titanium dioxide, methyl paraben, captan, propyl paraben, purified water

What the medicine looks like and what are the contents of the package:

Orange suspension packaged in 100 gram HDPE bottles

Manufacturer and license holder:

Taro Pharmaceutical Industries Ltd., 14 Hakitor Street, Haifa Bay 2624761

Registration number of the medicine in the National Drug Registry of the Ministry of Health: 01679.21210

This leaflet was checked and approved by the Ministry of Health in November 2016.