

**Patient leaflet in accordance with the Pharmacists'
Regulations (Preparations) – 1986**

This medicine is dispensed without a doctor's prescription

Sebosel

Suspension

Name and concentration of the active ingredient:

Each 1 ml contains:

selenium sulfide 25 mg

Inactive ingredients and allergens in this medicine: see section 2 under 'Important information about some of this medicine's ingredients', and section 6 'Additional information'.

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

Use this medicine according to the instructions in the section about dose in this leaflet. Consult a pharmacist if you need further information.

Consult your doctor if your condition does not improve or gets worse following or during the recommended treatment.

1. What is this medicine intended for?

To treat dandruff, seborrheic dermatitis on the scalp, and tinea versicolor.

Therapeutic group: antifungal.

This product works against dandruff in two ways:

- by reducing greasiness of the scalp
- by slowing down growth of the layer of skin cells on the scalp that cause dandruff.

2. Before using this medicine

Do not use this medicine if:

- You are sensitive (allergic) to the active ingredient (selenium sulfide) or to any of the other ingredients in this medicine (see Section 6).
- You have cracked, infected, or severely inflamed skin in the affected area, as this may cause absorption of selenium sulfide into your blood.

Special warnings about using this medicine

- Avoid contact of the medicine with the eyes. If the medicine accidentally gets in your eyes, rinse immediately with a lot of cold water.
- Sebosel is meant for external use only. Sebosel is not to be swallowed or eaten.
- 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.
- Remove gold, silver, or other metallic jewelry before use, because this medicine may cause discoloration.
- 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 keep the product away from metallic surfaces.

Children and adolescents

This medicine is not intended for infants and children. Safety and effectiveness in children have not been tested.

Interactions with other medicines

If you are taking or have recently taken other medicines, including nonprescription medicines and dietary supplements, tell your doctor or pharmacist.

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, think you may be pregnant or are planning to have a baby, consult your doctor or pharmacist before using this medicine.

Important information about some of this medicine's ingredients

Sebosel contains parabens (methyl paraben and propyl paraben), which may cause (possibly delayed) allergic reactions.

3. How to use this medicine?

Check with your doctor or pharmacist if you are not sure about your dose or about how to take this medicine.

The usually recommended dosage and manner of use are:

To treat tinea versicolor:

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

To treat dandruff and seborrheic dermatitis:

1. Massage a small amount (5-10 ml) of the suspension onto a damp scalp.
2. Leave on the scalp for 2 to 3 minutes.
3. Rinse the scalp thoroughly.
4. Repeat the process and rinse thoroughly.
5. After treatment, wash your hands thoroughly.
6. 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.

Consult your doctor if your condition does not improve or gets worse following/during the recommended treatment.

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 has accidentally swallowed some medicine, immediately see a doctor or go to a hospital emergency room and bring the medicine package with you. Swallowing Sebosel may cause nausea or vomiting.

Do not take medicines in the dark! Check the label and dose every time you take medicine. Wear glasses if you need them.

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

Side effects of unknown frequency (the frequency of these effects has not been established yet)

- Allergic reaction such as 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 and 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.
- Eye irritation, erosion of the cornea (eye pain, hyperemia, and temporary blindness) – may occur as a result of exposure of the eyes to Sebosel.

If you experience any side effect, 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 following the 'Reporting Side Effects of Drug Treatment' link on the Ministry of Health home page (www.health.gov.il), which opens an online form for reporting side effects, or you can also use this link: <https://sideeffects.health.gov.il>

5. How to store the medicine?

- Prevent poisoning! To prevent poisoning, keep this and all other medicines in a closed place out of the 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), which is stated on the package. The expiry date refers to the last day of that month.
- **Storage conditions:** Store below 25°C.
- Shelf-life after opening: 12 months.
- Do not throw away any 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 contents of the pack:

orange suspension packaged in a 30 or 100 gram plastic bottle.

Not all pack sizes may be marketed.

Manufacturer and license holder:

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

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

01679.21210

Revised in December 2023 according to Ministry of Health guidelines.

For further information about this medicinal product and for updated patient leaflets in Hebrew, Arabic and English, please scan the code:



<https://israeldrugs.health.gov.il/#!/medDetails/016%2079%2021210%2000>

For a printed copy of the patient information leaflet in English, please contact the registration holder by email Info@taro.com or by phone 1-800-464-664.