Summary of Product Characteristics

1. NAME OF THE MEDICINAL PRODUCT

Sebosel

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 1 ml of suspension contains 25 mg of selenium sulfide.

Excipients with known effect: methyl paraben and propyl paraben.

For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Orange suspension.

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

For the treatment of dandruff, seborrheic dermatitis of the scalp and tinea versicolor.

4.2 Posology and method of administration

Apply topically; scalp.

Adults and the elderly:

- **For tinea versicolor**

  Apply to affected areas and lather with a small amount of water. Allow product to remain on skin for 10 minutes, then rinse thoroughly. Repeat procedure once a day for seven days.

- **For seborrheic dermatitis and dandruff**

  Generally 2 applications each week for 2 weeks will control symptoms. Subsequently, Sebosel may be used less frequently – weekly, every 2 weeks, every 3 to 4 weeks.

  Should not be applied more frequently than necessary to maintain control.

Pediatric Use:

Safety and effectiveness in children have not been established.

4.3 Contraindications

- Hypersensitivity to the active substance (selenium sulfide) or to any of the excipients listed in section 6.1.
- Do not allow contact with broken or severely inflamed skin.

4.4 Special warnings and precautions for use

For external use only.

This suspension is an irritant to the eyes. It should therefore be kept away from the eyes.

If the suspension comes in contact with the eyes, they should rinse thoroughly with cold water. Exposure of Sebosel to eyes may result in ocular injuries such as corneal abrasion (see section 4.8).

Do not leave the suspension in contact with the hair or skin for more than the recommended duration as irritation, burning sensation or blistering may occur and do not use more often than recommended (see Section 4.2).
Sebosel is not to be ingested.
In the event of accidental ingestion, take all appropriate measures immediately.
Sebosel must not be applied to or on infected or broken skin as this may cause systemic absorption of the selenium sulfide.
Sebosel contains methyl paraben and propyl paraben, which can cause allergic reactions (possibly delayed).

4.5 Interaction with other medicinal products and other forms of interaction

If the hair has been damaged by chemical substances (like dyeing or bleaching products or as a result of a permanent wave or relaxing treatment) or if the hair is grey or white, discoloration of the hair may occur. In order to avoid discoloration of the hair it must be thoroughly rinsed immediately after use.

Sebosel should be very thoroughly rinsed from the hair before dyeing, tinting, or permanent waving the hair. It should not be applied for a period of two days before or after any of these procedures.

Gold, silver and other metallic jewelry should be removed prior to use of Sebosel, since discoloration of the metals may occur.

4.6 Fertility, pregnancy and lactation

Pregnancy

There are no adequate data from the use of selenium sulfide in pregnant women. Animal studies are insufficient with respect to effects on pregnancy, foetal development and postnatal development.
Breastfeeding
It is unknown if following external application selenium sulfide is excreted into breast milk. Therefore, Sebosel is not recommended for use while breastfeeding.

Avoid during pregnancy and breastfeeding.

4.7 Effects on ability to drive and use machines

No studies on the effects on the ability to drive or use machines have been performed.

4.8 Undesirable effects

Immune system disorder:

Frequency unknown:

Hypersensitivity, rash and urticarial

Skin and subcutaneous tissue disorders:

Frequency unknown:

Irritation and sensitization, sometimes described as a burning sensation.

Blistering can occur, especially if the suspension is kept in contact with hair or skin for longer than the recommended duration.

Alopecia can occur.

Hair color changes may occur; this can be avoided or minimized by thorough washing of the hair after treatment.

Seborrhea (oiliness of hair and scalp) or application site dryness may occur.

Eye disorders:

Not known:

Eye irritation.

Corneal abrasion* (see section 4.4).

*eye pain, hyperemia and transient blindness

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:

https://sideeffects.health.gov.il

4.9 Overdose

If ingested, vomiting should be provoked and general supportive measures given.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Selenium sulfide appears to have a cytostatic effect on cells of the epidermis and follicular epithelium, thus reducing corneocyte production. Sebosel acts as an antiseborrheic agent which effectively controls itching and scaling dandruff. It has activity against certain dermatophytes including *Pityrosporum orbiculare*, the organism causing pityriasis versicolor (tinea versicolor).

5.2 Pharmacokinetic properties

Not applicable.

5.3 Preclinical safety data

No additional preclinical information, relevant to the indication, is presented.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

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

6.2 Incompatibilities

Not known.

6.3 Shelf life

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

Shelf life after opening – 12 months.

6.4 Special precautions for storage

Store below 25°C.

6.5 Nature and contents of container

High density polyethylene bottles fitted with polypropylene caps, containing 30 or 100 grams.

Not all pack sizes may be marketed.

6.6 Special precautions for disposal and other handling

No special requirements

7. MARKETING AUTHORIZATION HOLDER

Taro Pharmaceutical Industry Ltd.
14 Hakitor St., Haifa Bay 2624761 Israel

8. MARKETING AUTHORIZATION NUMBER

016-79-21210-00

Revised in December 2023 according to MOHs guidelines.