

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 Sulphide.

3. PHARMACEUTICAL FORM

Shampoo.

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 to the 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, shampoo 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 any of the ingredients.
- Do not allow contact with broken or severely inflamed skin.

4.4 Special warnings and precautions for use

For external use only. Keep out of eyes; if Sebosel gets into the eyes, wash thoroughly with cold water.

Do not leave the shampoo 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.

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

There are no adequate data from the use of selenium sulphide in pregnant women. Animal studies are insufficient with respect to effects on pregnancy, foetal development and postnatal development.

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 shampoo 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.

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 sulphide appears to have a cytostatic effect on cells of the epidermis and follicular epithelium, thus reducing corneocyte production. Sebosel acts as an antiseborrhoeic 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

None 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 gram.

Not all pack sizes may be marketed.

6.6 Special precautions for disposal and other handling

No special requirements

7. MARKETING AUTHORISATION HOLDER

Taro Pharmaceutical Industry Ltd.

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Israel

8. MARKETING AUTHORISATION NUMBER

Sebosel 016-79-21210-00

Revised in January 2021 according to MOHs guidelines.