

רופא/ה נכבד/ה רוקח/ת נכבד/ת

חברת תרו מבקשת להודיעכם כי העלון לרופא של התכשיר Sebosel התעדכן.

בהודעה זו מצוינים רק הסעיפים בהם נעשו שינויים מהותיים בעלון לצרכן ובעלון לרופא. תוספות סומנו בצבע אדום. מחיקות בצבע כחול עם קו מחיקה.

העלון נשלח למשרד הבריאות לצורך פרסומו במאגר התרופות שבאתר משרד הבריאות: www.health.gov.il וניתן לקבלו מודפס על ידי פנייה לבעל הרישום:

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בברכה, מרינה גולדמן רוקחת ממונה

Sebosel, suspension

:מרכיב פעיל

Selenium sulfide 25 mg/ml

ההתוויה המאושרת לתכשיר:

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

עדכונים בעלון לרופא

4.4 Special warnings and precautions for use

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

4.8 Undesirable effects

תרו אינטרנשיונל בע"מ



Application to the skin or scalp may produce irritation or sensitisation, sometimes described as a burning sensation. Rarely, blistering can occur, especially if the shampoo is kept in contact with the skin for longer than the recommended duration.

An increase in the amount of normal hair loss can occur. Discoloration of the hair may occur; this can be avoided or minimised by thorough washing of the hair after treatment. As with other shampoos, oiliness or dryness of hair and scalp may occur.

Non-specific allergic reactions, including rash and urticaria, have been reported rarely.

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.