

PERRIGO

NDC 45802-040-64

Selenium Sulfide Lotion USP, 2.5%

For External Use Only
Shake Well Before Use

Rx Only

4 fl oz

PJL/BL/RK/F1

DESCRIPTION: A liquid antiseborrheic, antifungal preparation for topical application. Selenium Sulfide has the formula SeS_2 and has a molecular weight of 143.08.

CONTAINS: Selenium Sulfide 2.5%, Purified Water, Sodium Lauryl Sulfate, Ethylene Glycol Monostearate, Titanium Dioxide, Cocoamphocarboxyglycinate, Lauramide DEA, Bentonite, Sodium Phosphate (monobasic), Glyceryl Monoricinoleate, Fragrance, Citric Acid.

CLINICAL PHARMACOLOGY: Selenium Sulfide appears to have a cytostatic effect on cells of the epidermis and follicular epithelium, thus reducing corneocyte production.

INDICATION AND USAGE: For the treatment of dandruff and seborrheic dermatitis of the scalp. For treatment of tinea versicolor.

CONTRAINDICATIONS: This product should not be used by patients allergic to any of its components.

PRECAUTIONS: General: Should not be used when acute inflammation or exudation is present as increased absorption may occur.

Information for Patients: Application to skin or scalp may produce skin irritation or sensitization. If sensitivity reactions occur, use should be discontinued.

May be irritating to mucous membranes of the eyes and contact with this area should be avoided.

When applied to the body for treatment of tinea versicolor, Selenium Sulfide Lotion, USP 2.5% may produce skin irritation especially in the genital area and where skin folds occur. These areas should be thoroughly rinsed after application.

Carcinogenesis: Studies in mice using dermal application of 25% and 50% solutions of 2.5% Selenium Sulfide Lotion, over an 88 week period, indicated no carcinogenic effects.

Pregnancy: WHEN USED ON BODY SURFACES FOR THE TREATMENT OF TINEA VERSICOLOR, SELENIUM SULFIDE IS CLASSIFIED AS PREGNANCY CATEGORY "C". Animal reproduction studies have not been conducted with Selenium Sulfide Lotion. It is also not known whether Selenium Sulfide Lotion can cause fetal harm when applied to body surfaces of a pregnant woman or can affect reproduction capacity. Under ordinary circumstances Selenium Sulfide Lotion should

not be used for the treatment of tinea versicolor in pregnant women.

Pediatric Use: Safety and effectiveness in infants have not been established.

ADVERSE REACTIONS: In decreasing order of severity: skin irritation, occasional reports of increase in amount of normal hair loss, discoloration of hair (can be avoided or minimized by thorough rinsing of hair after treatment). As with other shampoos, oiliness or dryness of hair and scalp may occur.

OVERDOSAGE: Accidental Oral Ingestion: Selenium Sulfide Lotion is intended for external use only.

There have been no documented reports of serious toxicity in humans resulting from acute ingestion of Selenium Sulfide Lotion, however, acute toxicity studies in animals suggest that ingestion of large amounts could result in potential human toxicity.

For this reason, evacuation of the stomach contents should be considered in cases of acute oral ingestion.

DOSAGE AND ADMINISTRATION: See application instructions on rear panel of this bottle. For treatment of dandruff and seborrheic dermatitis: For the usual case, two applications each week for two weeks will afford control. After this, the lotion may be used at less frequent intervals - weekly, every two weeks, or even every 3 or 4 weeks in some cases. The preparation should not be applied more frequently than required to maintain control.

For treatment of 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 the body thoroughly. Repeat this procedure once a day for 7 days.

HOW SUPPLIED: Selenium Sulfide Lotion, USP 2.5% is available in 4 fl oz plastic bottles.

DISTRIBUTED BY PERRIGO®
ALLEGAN, MI 49010