SELENIUM SULFIDE- selenium sulfide lotion
Padagis Israel Pharmaceuticals Ltd

Selenium Sulfide Topical Suspension USP, 2.5% (Lotion)

For External Use Only

Shake Well Before Use

Rx Only

APPLICATION INSTRUCTIONS

Keep tightly capped. **SHAKE WELL BEFORE USING**.

Product may damage jewelry; remove jewelry before use.

For treatment of dandruff and seborrheic dermatitis of the scalp:

1. Massage about 1 or 2 teaspoonsful of suspension into wet scalp.
2. Allow to remain on scalp for 2 to 3 minutes.
3. Rinse scalp thoroughly.
4. Repeat application and rinse thoroughly.
5. After treatment, wash hands well.
6. Repeat treatments as directed by physician.

For treatment of tinea versicolor:

1. Apply to affected areas and lather with a small amount of water.
2. Allow to remain on skin for 10 minutes.
3. Rinse body thoroughly.
4. Repeat this procedure once a day for seven days.

DESCRIPTION

A liquid antiseborrheic, antifungal preparation for topical application. Selenium sulfide has the molecular formula SeS_2 and has a molecular weight of 143.09.

CONTAINS:

Selenium sulfide 2.5%; bentonite, citric acid, cocoamphocarboxyglycinate, ethylene glycol monostearate, fragrance, glycerol monoricinoleate, lauramide DEA, sodium lauryl sulfate, sodium phosphate (monobasic), titanium dioxide, and water.

CLINICAL PHARMACOLOGY

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

INDICATIONS AND USAGE

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

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 Topical Suspension USP, 2.5% (Lotion) 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 topical suspension, 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 Topical Suspension USP, 2.5% (Lotion). It is also not known whether Selenium Sulfide Topical Suspension USP, 2.5% (Lotion) can cause fetal harm when applied to body surfaces of a pregnant woman or can affect reproduction capacity. Under ordinary circumstances Selenium Sulfide Topical Suspension USP, 2.5% (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 Topical Suspension USP, 2.5% (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 Topical Suspension USP, 2.5% (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 suspension 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 seven days.

HOW SUPPLIED

Selenium Sulfide Topical Suspension USP, 2.5% (Lotion) is available as follows:

4 fl oz plastic bottle (NDC 45802-**040**-64)

WARNINGS AND PRECAUTIONS:

For External Use Only. Do not use on broken skin or inflamed areas. If allergic reactions occur, discontinue use. Avoid getting shampoo in eyes or in contact with genital area as it may cause irritation and burning.

KEEP THIS AND ALL MEDICATIONS OUT OF REACH OF CHILDREN.

Store at 20°-25°C (68°-77°F) [see USP Controlled Room Temperature].

Manufactured By Padagis, Minneapolis, MN 55427

www.padagis.com

Rev 12-21 A

27G26 RC F1/27G26 RC B1

Principal Display Panel

NDC 45802-**040**-64

Rx Only

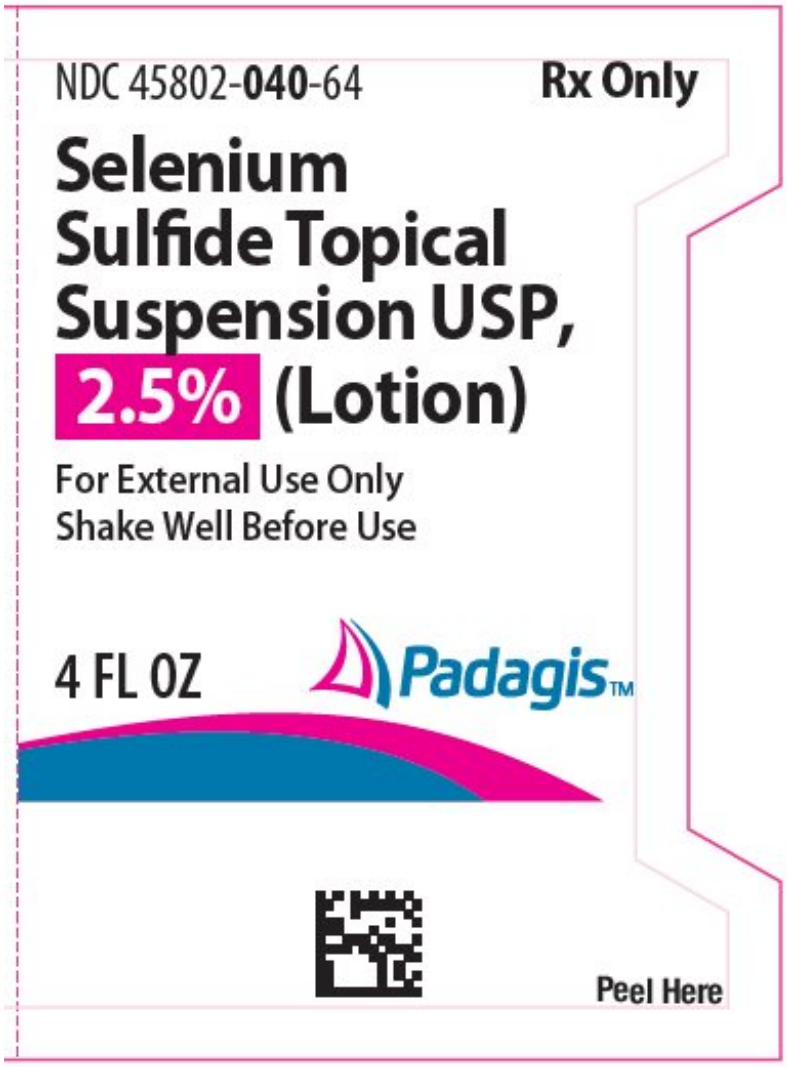
Selenium Sulfide Topical Suspension USP, 2.5% (Lotion)

For External Use Only

Shake Well Before Use

4 FL OZ

Peel Here



The following image is a placeholder representing the product identifier that is either affixed or imprinted on the drug package label during the packaging operation.

S/N [insert product's serial number]
Lot [insert product's lot number]
Exp [insert product's expiration date]

SELENIUM SULFIDE

selenium sulfide lotion

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:45802-040
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
SELENIUM SULFIDE (UNII: Z69D9E381Q) (SELENIUM SULFIDE - UNII:Z69D9E381Q)	SELENIUM SULFIDE	2.5 mg in 100 mL

Inactive Ingredients	
Ingredient Name	**Strength**
BENTONITE (UNII: A3N5ZCN45C)	
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	
GLYCOL STEARATE (UNII: 0324G66D0E)	
LAURIC DIETHANOLAMIDE (UNII: I29I2VHG38)	
SODIUM LAURYL SULFATE (UNII: 368GB5141J)	
SODIUM PHOSPHATE, MONOBASIC, UNSPECIFIED FORM (UNII: 3980JIH2SW)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
WATER (UNII: 059QF0KO0R)	

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:45802-040-64	118 mL in 1 BOTTLE; Type 0: Not a Combination Product	09/25/2006	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA089996	09/25/2006	

Labeler - Padagis Israel Pharmaceuticals Ltd (600093611)

Revised: 12/2021 Padagis Israel Pharmaceuticals Ltd