SELENIUM SULFIDE- selenium sulfide shampoo
Bi-Coastal Pharma International LLC

Disclaimer: This drug has not been found by FDA to be safe and effective, and this labeling has not been approved by FDA. For further information about unapproved drugs, click here.

Selenium Sulfide
2.25% Shampoo

Rx Only

DIRECTIONS

A liquid antiseborrehic, antifungal preparation for topical application.

Each mL of Selenium Sulfide 2.25% Shampoo contains 22.5 mg selenium sulfide, ammonium lauryl sulfate, caprylic/capric triglyceride, chromium oxide green, citric acid, cocamidopropyl betaine, D&C yellow #8, diazolidinyl urea, edetate disodium, FD&C red #40, fragrance, hydroxypropyl methylcellulose, magnesium aluminum silicate, methylparaben, panthenol, PPG-2 hydroxyethyl coco/isostearamide, propylene glycol, propylparaben, purified water, sodium citrate, titanium dioxide, tocopheryl acetate, urea, zinc pyrithione.

CLINICAL PHARMACOLOGY

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

PHARMACOKINETICS

The mechanism of action of topically applied selenium sulfide is not yet known.

INDICATIONS & USAGE

A liquid antiseborrheic, antifungal preparation for the treatment of seborrheic dermatitis of the scalp, dandruff and tinea versicolor. Urea hydrates and is useful for conditions such as dry scalp.

CONTRAINDICATIONS

Contraindicated in persons with known or suspected hypersensitivity to any of the listed ingredients.

WARNINGS

For external use only. Not for ophthalmic use. **DO NOT USE ON BROKEN SKIN OR INFLAMED AREAS.** If allergic reaction occurs, discontinue use. Avoid contact with eyes, genital areas and skin folds, as irritation and burning may result. If accidental contact occurs, rinse thoroughly with water.

PRECAUTIONS

This medication is to be used as directed by a physician. Not to be used when inflammation or exudation is present as increased absorption may occur.

CARCINOGENESIS

Dermal application of 25% and 50% solutions of 2.5% selenium sulfide lotion on mice over an 88-week

period indicated no carcinogenic effects.

USE IN PREGNANCY

CATEGORY C

Animal reproduction studies have not been conducted with this medication. It is also not known whether this product can cause fetal harm when applied to the body surfaces of a pregnant woman or can affect reproduction capacity. Under ordinary circumstances, selenium sulfide 2.25% shampoo should not be used by pregnant women.

NURSING MOTHERS

It is not known whether or not this drug is secreted in human milk. Because many drugs are secreted in human milk, caution should be exercised when this product is administered to a nursing woman.

PEDIATRIC USE

Safety and effectiveness in children have not been established.

ADVERSE REACTIONS

In decreasing order of severity: skin irritation; occasional reports of increase in 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

There are no documented reports of serious toxicity in humans resulting from acute ingestion of selenium sulfide 2.25% shampoo. However, acute toxicity studies in animals suggest that ingestion of large amounts could result in potential human toxicity. Evacuation of the stomach contents should be considered in cases of acute oral ingestion.

DOSAGE AND ADMINISTRATION

SHAKE WELL BEFORE USING

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 or as directed by a physician. Should not be applied more frequently than necessary to maintain control.

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 or as directed by a physician.

HOW SUPPLIED

Selenium Sulfide 2.25% Shampoo is supplied in 180 mL bottles, NDC 42582-900-06.

Store at 20°C to 25°C (68°F to 77°F), excursions permitted between 15°C and 30°C (between 59°F and 86°F). Brief exposure to temperatures up to 40°C (104°F) may be tolerated provided the mean kinetic temperature does not exceed 25°C (77°F); however, such exposure should be minimized. Protect from freezing.

KEEP THIS AND ALL MEDICATIONS OUT OF THE REACH OF CHILDREN.

Manufactured for:
Bi-Coastal Pharma International LLC
Red Bank, New Jersey 07701 USA

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PRINCIPAL DISPLAY PANEL - 180 mL Bottle Carton

NDC 42582-900-06

Rx Only

For topical use only
Not for ophthalmic use

Selenium
Sulfide 2.25%
Shampoo

180 mL

Bi-Coastal Pharma International LLC

SELENIUM SULFIDE

selenium sulfide shampoo

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:42582-900
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
Selenium Sulfide (UNII: Z69D9E381Q) (Selenium Sulfide - UNII:Z69D9E381Q)	Selenium Sulfide	22.5 mg in 1 mL

Inactive Ingredients

Ingredient Name	Strength
ammonium lauryl sulfate (UNII: Q7AO2R1M0B)	
medium-chain triglycerides (UNII: C9H2L21V7U)	
chromic oxide (UNII: X5Z09SU859)	
citric acid monohydrate (UNII: 2968PHW8QP)	
cocamidopropyl betaine (UNII: 5OCF3O11KX)	
fluorescein sodium (UNII: 93X55PE38X)	
diazolidinyl urea (UNII: H5RIZ3MPW4)	
edetate disodium (UNII: 7FLD91C86K)	
FD&C red no. 40 (UNII: WZB9127XOA)	
HYPROMELLOSE, UNSPECIFIED (UNII: 3NXW29V3WO)	
magnesium aluminum silicate (UNII: 6M3P64V0NC)	
methylparaben (UNII: A2I8C7HI9T)	
panthenol (UNII: WV9CM0O67Z)	
PPG-2 hydroxyethyl coco/isostearamide (UNII: EK4J71ZKEQ)	
propylene glycol (UNII: 6DC9Q167V3)	
propylparaben (UNII: Z8IX2SC1OH)	
water (UNII: 059QF0KO0R)	
SODIUM CITRATE, UNSPECIFIED FORM (UNII: 1Q73Q2JULR)	
titanium dioxide (UNII: 15FIX9V2JP)	
.alpha.-tocopherol acetate (UNII: 9E8X80D2L0)	
urea (UNII: 8W8T17847W)	
pyrithione zinc (UNII: R953O2RHZ5)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:42582-900-06	1 in 1 CARTON	06/01/2011	
1		180 mL in 1 BOTTLE; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
UNAPPROVED DRUG OTHER		06/01/2011	

Labeler - Bi-Coastal Pharma International LLC (078397428)