SELENIUM SULFIDE- selenium sulfide shampoo
Westminster Pharmaceuticals, 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

DESCRIPTION

Each mL of Selenium Sulfide 2.25% Shampoo contains 22.5mg selenium sulfide, and the following inactive ingredients: butylated hydroxytoluene, cetyl alcohol, citric acid, cocamidopropyl betaine, disodium EDTA, D&C yellow No. 10, FD&C red No. 40, fragrance, panthenol, phenoxyethanol, propylene glycol, purified water, pyrithione zinc, sodium laureth sulfate, sodium thiosulfate, stearyl alcohol, tocopherol acetate, triacetin, urea, xanthan gum.

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

This product is contraindicated in persons with known or suspected hypersensitivity to any of the ingredients of the product.

WARNINGS

KEEP OUT OF REACH OF CHILDREN. FOR EXTERNAL USE ONLY. NOT FOR OPHTHALMIC USE.

PRECAUTIONS

General

This product is to be used as directed by a physician and should not be used to treat any condition other than that for which it was prescribed. If redness or irritation occurs, discontinue use and consult a physician.

Information for Patients

Patients should discontinue the use of this product if the condition becomes worse or if a rash develops in the area being treated or elsewhere. Avoid contact with eyes, lips and mucous membranes. If accidental contact occurs, rinse thoroughly with water. Do not use on broken skin or inflamed areas.

Carcinogenesis, Mutagenesis and Impairment of Fertility

Dermal application of 25% and 50% solutions of 2.5% selenium sulfide lotion on mice over an 88-week period indicated no carcinogenic effects. Studies on reproduction and fertility also have not been performed.

Pregnancy

CATEGORY C

Animal reproduction studies have not been conducted with this product. It is also not known whether this product can affect reproduction capacity or cause fetal harm when administered to a pregnant woman. 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 under the age of 12 years 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. To report a serious adverse event, please contact Westminster Pharmaceuticals at 1-844-221-7294 or call FDA at 1-800-FDA-1088 or fda.gov/medwatch.

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

Wet skin and apply to areas to be cleansed. Massage gently into the skin working into a full lather. Rinse thoroughly and pat dry. Generally two applications each week for two weeks will control symptoms. Subsequently, shampoo may be used less frequently, or as directed by a physician. It should not be applied more frequently than necessary to maintain control.

For tinea versicolor

Wet skin and apply to areas to be cleansed. Massage gently into the skin working into a full lather. Allow product to remain on skin for ten minutes, then rinse thoroughly and pat dry. Repeat procedure once a day for seven days or as directed by a physician.

STORAGE

Store at 20°C to 25°C (68°F to 77°F), excursions permitted between 15°C to 30°C (between 59°F to 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.

NOTICE: Protect from freezing and excessive heat. Keep bottle tightly closed.

HOW SUPPLIED

Selenium Sulfide 2.25% Shampoo is supplied in 180mL bottles, NDC 69367-229-18.

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

Manufactured for:
Westminster Pharmaceuticals, LLC
Nashville, TN 37217
Rev. 09/22

PRINCIPAL DISPLAY PANEL - 180 mL Bottle Label

NDC 69367-229-18

Rx Only

SELENIUM
SULFIDE

2.25%

Shampoo

with urea and
zinc pyrithione

6 fl. oz. (180 mL)

Westminster
Pharmaceuticals

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SELENIUM SULFIDE

selenium sulfide shampoo

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:69367-229
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
SODIUM LAURETH-3 SULFATE (UNII: BPV390UAP0)	
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
COCAMIDOPROPYL BETAINE (UNII: 5OCF3O11KX)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	
D&C YELLOW NO. 10 (UNII: 35SW5USQ3G)	
PANTHENOL (UNII: WV9CM0O67Z)	
WATER (UNII: 059QF0KO0R)	
PYRITHIONE ZINC (UNII: R953O2RHZ5)	
UREA (UNII: 8W8T17847W)	
XANTHAN GUM (UNII: TTV12P4NEE)	
BUTYLATED HYDROXYTOLUENE (UNII: 1P9D0Z171K)	
CETYL ALCOHOL (UNII: 936JST6JCN)	
SODIUM THIOSULFATE (UNII: HX1032V43M)	
STEARYL ALCOHOL (UNII: 2KR89I4H1Y)	
TRIACETIN (UNII: XHX3C3X673)	
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:69367-229-18	180 mL in 1 BOTTLE; Type 0: Not a Combination Product	09/09/2019	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
UNAPPROVED DRUG OTHER		09/09/2019	

Labeler - Westminster Pharmaceuticals, LLC (079516651)

Revised: 1/2023 Westminster Pharmaceuticals, LLC