SELENIUM SULFIDE- selenium sulfide shampoo
Laser 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.

Rx Only
Selenium Sulfide 2.25% Shampoo

DESCRIPTION: A liquid antiseborrheic, antifungal preparation for topical application. Each mL of **Selenium Sulfide 2.25% Shampoo** contains 22.5 mg selenium sulfide, and the following inactive ingredients: Alpha-tocopheryl acetate, ammonium lauryl sulfate, butylated hydroxytoluene, cetyl alcohol, cocamidopropyl betaine, disodium EDTA, D&C yellow #10, FD&C red #40, fragrance, methylparaben, panthenol, propylene glycol, propylparaben, purified water, pyrithione zinc, sodium thiosulfate, stearyl alcohol, triacetin, urea, and 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: 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. **KEEP THIS AND ALL MEDICATIONS OUT OF THE REACH OF CHILDREN.**

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:* Wet skin and apply to affected areas. Massage gently into skin working to a full lather. 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 6 fluid oz. (180 mL) bottles, NDC 16477-422-06. Store at 20° - 25°C (68° - 77°F), excursions permitted to 15° - 30°C (59° - 86°F). [See USP Controlled Room Temperature]. 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.

All prescription substitutions and / or recommendations using this product shall be made subject to state and federal statutes as applicable. **Please NOTE: This is not an Orange Book product and has not been subjected to FDA therapeutic equivalency or other equivalency testing. No representation is made as to generic status or bioequivalency.** Each person recommending a prescription substitution using this product shall make such recommendations based on each such person’s professional opinion and knowledge, upon evaluating the active ingredients, inactive ingredients (excipients) and other chemical information provided herein.

Manufactured for:
Laser Pharmaceuticals, LLC
Alpharetta, GA 30004
401165-02 Rev 12/2024

NDC 16477-422-06

Rx Only

Selenium

Sulfide

2.25%

Shampoo

6 fluid oz. (180 mL)

FOR TOPICAL USE ONLY

NOT FOR OPTHALMIC USE

LASER

NDC 16477-422-06
RX ONLY

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Dosage and Administration:
SHAKE WELL BEFORE USING

For seborrheic dermatitis and dandruff:
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See inside label for full product information.
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401165-02 Rev. 12/2024

PEEL

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LASERx

Manufactured for:
Laser Pharmaceuticals, LLC
Alpharetta, GA 30004
401165-02 Rev. 12/2024

SELENIUM SULFIDE

selenium sulfide shampoo

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:16477-422
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
PYRITHIONE ZINC (UNII: R953O2RHZ5)	
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
UREA (UNII: 8W8T17847W)	
BUTYLATED HYDROXYTOLUENE (UNII: 1P9D0Z171K)	
CETYL ALCOHOL (UNII: 936JST6JCN)	

AMMONIUM LAURYL SULFATE (UNII: Q7AO2R1M0B)	
COCAMIDOPROPYL BETAINE (UNII: 5OCF3O11KX)	
EDETATE DISODIUM ANHYDROUS (UNII: 8NLQ36F6MM)	
METHYLPARABEN (UNII: A2I8C7HI9T)	
PROPYLPARABEN (UNII: Z8IX2SC1OH)	
D&C YELLOW NO. 10 (UNII: 35SW5USQ3G)	
SODIUM THIOSULFATE (UNII: HX1032V43M)	
TRIACETIN (UNII: XHX3C3X673)	
XANTHAN GUM (UNII: TTV12P4NEE)	
PANTHENOL (UNII: WV9CM0O67Z)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
WATER (UNII: 059QF0KO0R)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	
STEARYL ALCOHOL (UNII: 2KR89I4H1Y)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:16477-422-06	180 mL in 1 BOTTLE; Type 0: Not a Combination Product	04/11/2022	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
unapproved drug other		04/11/2022	

Labeler - Laser Pharmaceuticals, LLC (614417132)

Revised: 11/2025 Laser Pharmaceuticals, LLC