SELENIUM SULFIDE - selenium sulfide shampoo Rochester Pharmaceuticals

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.

DESCRIPTION

Rx Only

Selenium Sulfide 2.25% Shampoo

A liquid antiseborrehic, antifungal preparation for topical application.

Each gram of Selenium Sulfide 2.25% Shampoo contains 22.5mg selenium sulfide, ammonium lauryl sulfate, caprylic/capric triglyceride, chromium oxide greens, citric acid, cocamidopropyl betaine, D and C yellow No. 8, diazolidinyl urea, edetate disodium, FD and C red No. 40, fragrance, hydroxypropylmethylcellulose, magnesium aluminum silicate, methylparaben, panthenol, PPG-2 hydroxyethyl coco/isostearamide, propyleneglycol, propylparaben, purified water, sodium citrate, titanium dioxide, tocopheryl acetate, urea and zinc pyrithione.

CLINICAL PHARMACOLOGY

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

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 49908-146-80.

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: Rochester Pharmaceuticals Rochester, NY 14624 1-866-458-1772 www.RochesterPharm.com

SSS-PI-0912

Package Label

NDC 49908-146-80

Rx Only

For topical use only Not for ophthalmic use

Selenium Sulfide 2.25% Shampoo

180 mL



Ingredients: 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 and zinc pyrithione.

Dosage and Administration: SHAKE WELL BEFORE USING

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See insert for full Prescribing Information.

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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). Protect from freezing.

Manufactured for: Rochester Pharmaceuticals Rochester, NY 14624 1-886-458-1772 www.RochesterPharm.com



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Selenium Suinde 2.25% Shampoo

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NDC 48808-148-80

Mx Only

For topical use only Not for opiritalmic use

Selenium Sulfide 2.25% Shampoo

180 mL

Rochester

Store at 20° C to 26° C (66° F to 77° F), escurations permittied between 15° C and 30° C (between 59° F and 86° F). Protect from freezing.

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

Manufactured for: Rochaster Phermacouficaia Rochaster, NY 14624 1-866-458-1772 www.RocksterPherm.co.

Rochester



NDC 48908-148-80

Rx Only

For topical use only Not for ophthalmic use

Selenium Suifide 2.25% Shampoo

180 mL

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Ingrediente: Each ml. of Selentem Suitide 2.28% Shampou certains 22.5 mg selentem seitide, ammanium inunyi matide, capylie/sapric trighyoride, chromium catde green, citric acid, recurridapropri lestatne, D&C yellow 814, discoldinyi ama, edetate disastum, FD&C md 444, requence, hydroxypropyi mentipliculuses, magnesium atuminum stiliculu, methytembeu, parvitemol, PFG-2 hydroxyellyi cocarlinosineramida, propylene gipcol, propyleneben, purified eciter, podium stiliculus, illumium diadde, tecopheryl eciter, podium stiliculus, illumium diadde, tecopheryl eciter, uma and zinc pyrithium.

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SELENIUM SULFIDE

selenium sulfide shampoo

Product Information					
Product Type	HUMAN PRESCRIPTION DRUG LABEL	Item Code (Source)	NDC:49908- 146		
Route of Administration	TOPICAL	DEA Schedule			

Active Ingredient/Active Moiety				
Ingredient Name	Basis of Strength	Strength		
SELENIUM SULFIDE (SELENIUM SULFIDE)	SELENIUM SULFIDE	22.5 mg in 1 mL		

Inactive Ingredients			
Ingredient Name	Strength		
Ammonium Lauryl Sulfate			
medium-chain triglycerides			
chromium dioxide			
Cocamidopropyl Betaine			
D&C Yellow NO. 8			
Diazolidinyl Urea			
edetate disodium			
FD&C RED NO. 40			
Hypromellose 2208 (100 MPA.S)			
magnesium aluminum silicate			
methylparaben			
panthenol			
propylene glycol			
propylparaben			
water			
sodium citrate			
titanium dioxide			
ALPHA-TO COPHEROL ACETATE			
urea			
pyrithione zinc			

Packaging				
# Item Code	Package Description	Marketing Start Date	Marketing End Date	
1 NDC:49908-146-80	1 in 1 CARTON			
1	180 mL in 1 BOTTLE, PLASTIC			

Marketing Information					
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date		
unapproved drug other		03/30/2011			

Labeler - Rochester Pharmaceuticals (069874500)

Revised: 2/2013 Rochester Pharmaceuticals