SELENIUM SULFIDE- selenium sulfide shampoo
KMM 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 2.3% Shampoo

Rx Only

FOR EXTERNAL USE ONLY. NOT FOR OPHTHALMIC USE.

DESCRIPTION:

Each mL contains 23 mg of selenium sulfide in a vehicle consisting of: D&C yellow #8, FD&C red #40, fragrance, methyl paraben, PEG-150 pentaerythrityl tetrastearate (and) aqua (and) PEG-6 caprylic/capric glycerides, propyl paraben, propylene glycol, purified water, sodium chloride, sodium laureth sulfate (and) cocamidopropyl betaine (and) sodium lauryl sulfate (and) cocamide MIPA, titanium dioxide, urea and 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:

This product is a liquid antiseborrheic, antifungal preparation useful 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.

PRECAUTIONS:

FOR EXTERNAL USE ONLY. NOT FOR OPHTHALMIC USE.

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.

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. This product should be used by a pregnant woman only if clearly needed or when potential benefits outweigh potential hazards to the fetus.

Nursing Mothers: It is not known whether this drug is excreted in human milk. Because many drugs are excreted 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.

OVERDOSAGE:

There are no documented reports of serious toxicity in humans resulting from acute ingestion of this product. 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 use.

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. The product may darken upon storage. Discoloration does not impair the efficacy or safety of the product. Keep container tightly closed.

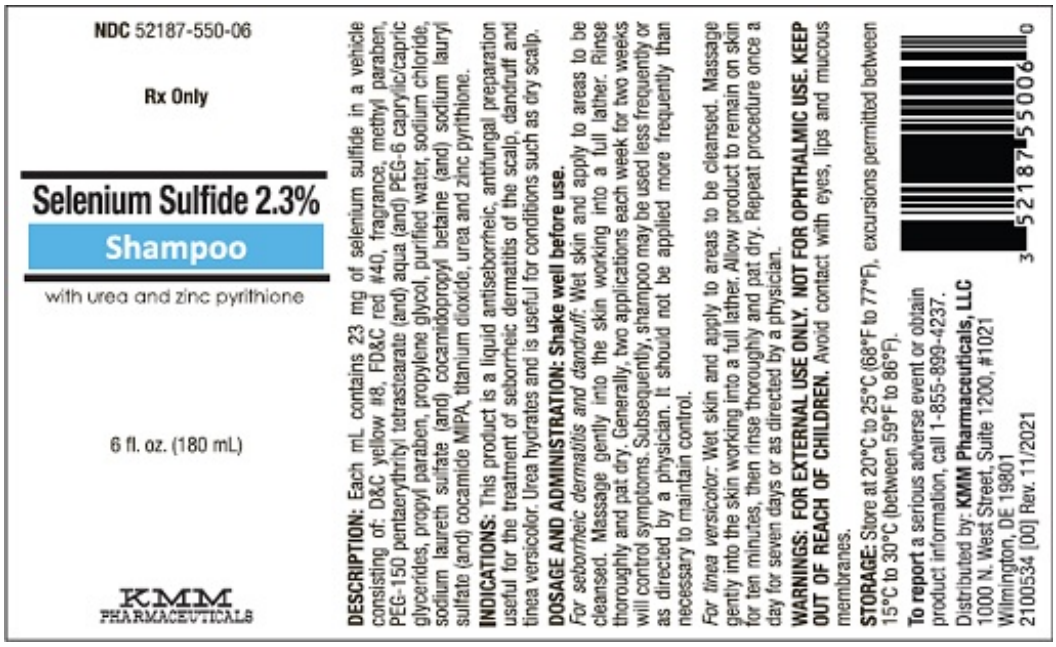
HOW SUPPLIED:

This product is supplied in the following size(s):

6 fl. oz. (180 mL) bottles, **NDC** 52187-550-06

To report a serious adverse event or obtain product information, call 1-855-899-4237.

Distributed by:
KMM Pharmaceuticals, LLC
1000 N. West Street
Suite 1200, #1021
Wilmington, DE 19801
2100535 [00] Rev. 11/2021



SELENIUM SULFIDE

selenium sulfide shampoo

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:52187-550
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
SELENIUM SULFIDE (UNII: Z69D9E381Q) (SELENIUM SULFIDE - UNII:Z69D9E381Q)	SELENIUM SULFIDE	23 mg in 1 mL

Product Characteristics

Color	brown (tan orange)	**Score**	
Shape		**Size**	
Flavor		**Imprint Code**	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:52187-550-06	180 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	02/28/2022	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
unapproved drug other		02/28/2022	

Labeler - KMM Pharmaceuticals, LLC (078521761)

Revised: 2/2022 KMM Pharmaceuticals, LLC