

SELENIUM SULFIDE- selenium sulfide shampoo
Bryant Ranch Prepack

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

FOR EXTERNAL USE ONLY. NOT FOR OPHTHALMIC USE.

DESCRIPTION:

Each mL contains 23 mg of selenium sulfide in a vehicle consisting of: ammonium lauryl sulfate, caprylic/capric triglyceride, chromium oxide green, citric acid, cocamidopropyl betaine, D&C yellow no 8, diazolidinyl urea, distearyl phthalic acid amide, edetate disodium, fragrance, hydroxypropyl methylcellulose, magnesium aluminum silicate, methylparaben, panthenol, PPG-2 hydroxyethyl coco/isostearamide, propylene glycol, propylparaben, purified water, FD&C red no 40, 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 corneocyte production.

Pharmacokinetics:

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

INDICATIONS:

Selenium Sulfide 2.3% Shampoo 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:

Selenium Sulfide 2.3% Shampoo is contraindicated in persons with known or suspected hypersensitivity to any of the ingredients of the product.

WARNINGS:

PRECAUTIONS: FOR EXTERNAL USE ONLY. NOT FOR OPHTHALMIC USE.

Avoid contact with eyes, lips and mucous membranes.

General:

Selenium Sulfide 2.3% Shampoo is to be used as directed by a licensed medical practitioner 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 licensed medical practitioner.

Information for Patients:

Patients should discontinue the use of Selenium Sulfide 2.3% Shampoo 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.

Call your licensed medical practitioner for medical advice about side effects. To report a serious adverse event, call 1-888-767-7913.

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:

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 licensed medical practitioner. 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 licensed medical practitioner.

HOW SUPPLIED:

Selenium Sulfide 2.3% Shampoo is supplied in a 6 fl. oz. (180 mL) bottle, NDC 63629-2002-1.

STORAGE:

Store at 20-25°C (68-77°F); excursions permitted between 15° and 30°C (59° and 86°F). See USP Controlled Room Temperature.

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

All prescriptions using this product shall be pursuant to state statutes as applicable. This is not an Orange Book product. This product has not been evaluated for therapeutic equivalence.

KEEP OUT OF REACH OF CHILDREN

Rx only

Manufactured for:

Cameron Pharmaceuticals, LLC 1009 Twilight Trail

Frankfort, Kentucky 40601

Rev. 08/2015

Selenium Sulfide 2.3% Shampoo, #180



GTIN
Lot
Exp
SN

Relabeled by:
Bryant Ranch Prepack, Inc.
Burbank, CA 91504 USA

Manufactured by:
Cameron Pharmaceuticals, LLC
Louisville, KY 40245

Each mL contains: Selenium Sulfide, 23 mg/ml

Keep this and all medication out of the reach of children.

Store at 20° to 25°C (68° to 77°F) [See USP Controlled Room Temperature].

FOR EXTERNAL USE ONLY

NOT FOR OPHTHALMIC USE

6362920021

NDC 63629-2002-1

Selenium Sulfide
Shampoo

2.3%



Rx only
180 mL

SELENIUM SULFIDE

selenium sulfide shampoo

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:63629-2002(NDC:42494-336)
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

Inactive Ingredients

Ingredient Name	Strength
AMMONIUM LAURYL SULFATE (UNII: Q7AO2R1M0B)	
TRICAPRIN (UNII: O1PB8EU98M)	
CHROMIC OXIDE (UNII: X5Z09SU859)	
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	
COCAMIDOPROPYL BETAINE (UNII: 5OCF3O11KX)	
FLUORESCEIN SODIUM (UNII: 93X55PE38X)	
DIAZOLIDINYL UREA (UNII: H5RIZ3MPW4)	
DISTEARYL PHTHALAMIC ACID (UNII: 5552GSZ9LI)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	
HYPROMELLOSE, UNSPECIFIED (UNII: 3NXW29V3WO)	
MAGNESIUM ALUMINUM SILICATE (UNII: 6M3P64V0NC)	
METHYLPARABEN (UNII: A2I8C7HI9T)	
PANTHENOL (UNII: WW9CM0067Z)	
PPG-2 HYDROXYETHYL COCO/ISOSTEARAMIDE (UNII: EK4J71ZKEQ)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
PROPYLPARABEN (UNII: Z8IX2SC1OH)	

WATER (UNII: 059QF0KO0R)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	
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:63629-2002-1	180 mL in 1 BOTTLE; Type 0: Not a Combination Product	07/01/2021	

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
unapproved drug other		04/20/2018	

Labeler - Bryant Ranch Prepack (171714327)

Registrant - Bryant Ranch Prepack (171714327)

Establishment			
Name	Address	ID/FEI	Business Operations
Bryant Ranch Prepack		171714327	REPACK(63629-2002) , RELABEL(63629-2002)