CVS PHARMACY DANDRUFF MOISTURIZING WITH ALOE- selenium sulfide shampoo CVS Pharmacy Inc

Disclaimer: Most OTC drugs are not reviewed and approved by FDA, however they may be marketed if they comply with applicable regulations and policies. FDA has not evaluated whether this product complies.

Active Ingredient

Selenium Sulfide 1%

Purpose

Anti-Dandruff

Uses

Controls flaking, scaling and itching associated with dandruff

Warnings

For external use only

Do Not Use

- On scalp that is broken or inflamed.
- If you are allergic to ingredients in this product

When using this product

avoid contact with eyes. If contact occurs, rinse with water. For use on color treated or permed hair, rinse thoroughly

Stop using this product and ask doctor if

- rash appears
- condition worsens or does not improve in 2-4 weeks

Keep out of reach of children

In case of accidental ingestion, get medical help or contact a Poison Control Center immediately

If pregnant or breast feeding

ask a doctor before use

Directions

- Adults and children 12 years and over: wet hair thoroughly, apply shampoo, generously lather, rinse thoroughly. Repeat. Use every 3-4 days for up to 8 weeks or as directed by a doctor. Then use only as needed to control dandruff.
- Children under 12 years: ask a doctor

Other Information

- store between 35° and 85° F (2° and 30°C)
- protect from freezing

• see bottom of bottle for lot number and expiration date

Inactive Ingredients

Water (Aqua), Ammonium Lauryl Sulfate, Ammonium Laureth Sulfate, Dihydrogenated Tallow Phthalic Acid Amide, Cocamide DEA, Fragrance (Parfum), Titanium Dioxide, Dimethicone, Hydroxypropyl Methylcellulose, Citric Acid, Sodium Isostearoyl Lactylate, DMDM Hydantoin, Aloe Barbadensis Leaf Juice, Sodium Citrate, Sodium Chloride, Blue 1 (CI 42090)

Package Front and Back Labels ra11.jpg





anti-dandruff shampoo

Drug Facts

Active Ingredient Selenium Sulfide 1%

Purpose

Uses controls flaking, scaling and ltching associated with

Warnings For external use only

Do not use . on scalp that is broken or inflamed . if you are allergic to ingredients in this product

When using this product * avoid contact with eyes * if product gets into eyes, rinse thoroughly with water

Stop use and ask a doctor if * rash appears * condition worsens or does not improve in 2-4 weeks

If pregnant or breast-feeding, ask a doctor before use. Keep out of the reach of children. If swallowed, get medical help or contact a Poison Control Center right

Directions

DIFECTIONS

Adults and Children 12 years and over:
wet hair thoroughly, apply shampoo, generously lather,
inse thoroughly, Repeat. Use every 9-4 days for up to 8
weeks or as directed by a doctor. Then use only as
needed to control dandruff.

Children under 19 weers ask a doctor.

Children under 12 years: ask a doctor

Other Information • store between 35" and 86"F (2° and 30°C) • protect from light • protect from freezing • see bottom of bottle for lot number and expiration date

Inactive ingredients Water, Armonium Lauryl Sulfate, Ammonium Laureth Sulfate, Dihydrogenated Tallow Phthalic Acid Amide, Cocamide DEA, Fragrance, Thanium Doxide, Dimetricone, Hydroxypropyl Methyl-cellulose, Citin Acid, Sodium Isostearryl Lachylate, DMDM Hydantoin, Aloe Barbadensis Leaf Juice, Sodium Citrate, Sodium Chloride, Blue 1

"Product is not manufactured or distributed by Chattam Inc., distributer of Selsun Blue® Shampoo Distributer of Selsun Blue® Shampoo Distributed by CVS Pharmacy, Inc. Woonsocket, Pl. 02895 © 2006 CVS/pharmacy www.cvs.com anufactured by: Apolo Health and Beauty Care 1-866-695-3030 Product of Canada.





CVS PHARMACY DANDRUFF MOISTURIZING WITH ALOE

selenium sulfide shampoo

Product Information

Product Type

HUMAN OTC DRUG

Item Code (Source)

NDC:59779-611

Route of Administration

TOPICAL

l	Active Ingredient/Active Moiety				
l	Ingredient Name	Basis of Strength	Strength		
l	SELENIUM SULFIDE (UNII: Z69D9E381Q) (SELENIUM - UNII:H6241UJ22B)	SELENIUM SULFIDE	1 mL in 100 mL		

Inactive Ingredients	
Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
AMMO NIUM LAURYL SULFATE (UNII: Q7AO2R1M0B)	
AMMO NIUM LAURETH-2 SULFATE (UNII: 698O4Z48G6)	
COCO DIETHANOLAMIDE (UNII: 92005F972D)	
TITANIUM DIO XIDE (UNII: 15FIX9 V2JP)	
DIMETHICO NE (UNII: 92RU3N3Y1O)	
HYPROMELLOSE 2208 (100 MPA.S) (UNII: B1QE5P712K)	
CITRIC ACID MONO HYDRATE (UNII: 2968 PHW8 QP)	
SODIUM ISOSTEARO YL LACTYLATE (UNII: 8730 J0 D3EV)	
DMDM HYDANTO IN (UNII: BYR0 546 TOW)	
ALOE VERA LEAF (UNII: ZY8 1Z8 3H0 X)	
SODIUM CITRATE (UNII: 1Q73Q2JULR)	
SODIUM CHLORIDE (UNII: 451W47IQ8X)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	

Packaging						
Package Description	Marketing Start Date	Marketing End Date				
25 mL in 1 BOTTLE, PLASTIC						
	8 1					

Marketing Information						
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date			
OTC monograph final	part358H	10/15/2010				

Labeler - CVS Pharmacy Inc (062312574)

Registrant - Apollo Health and Beauty Care (201901209)

Establishment					
Name	Address	ID/FEI	Business Operations		
Apollo Health and Beauty Care		201901209	manufacture		

Revised: 10/2010 CVS Pharmacy Inc