

**EQUALINE MENTHOL- selenium sulfide liquid
SUPERVALU 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.

DRUG FACTS

ACTIVE INGREDIENT

SELENIUM SULFIDE 1%

PURPOSE

ANTI-DANDRUFF, ANTI-SEBORRHEIC DERMATITIS

USES

FOR RELIEF OF FLAKING AND ITCHING ASSOCIATED WITH DANDRUFF AND SEBORRHEIC DERMATITIS AND TO HELP PREVENT THE CHANCE OF RE-OCCURRENCE.

WARNINGS

FOR EXTERNAL USE ONLY.

ASK A DOCTOR BEFORE USING IF YOU HAVE

SEBORRHEIC DERMATITIS IN AREAS OTHER THAN THE SCALP.

WHEN USING THIS PRODUCT

AVOID CONTACT WITH EYES. IF PRODUCT GETS INTO EYES, RINSE THOROUGHLY WITH WATER. FOR USE ON COLOR TREATED OR PERMED HAIR, RINSE THOROUGHLY.

STOP USING THIS PRODUCT AND ASK A DOCTOR IF

CONDITION WORSENS OR DOES NOT IMPROVE AFTER REGULAR USE OF THIS PRODUCT AS DIRECTED.

KEEP OUT OF REACH OF CHILDREN.

IN CASE OF ACCIDENTAL INGESTION, GET MEDICAL HELP OR CONTACT A POISON CONTROL CENTER IMMEDIATELY.

DIRECTIONS

SHAKE WELL, APPLY SHAMPOO, AND RINSE THOROUGHLY. FOR BEST RESULTS, USE AT LEAST TWICE A WEEK OR AS DIRECTED BY A DOCTOR.

INACTIVE INGREDIENTS:

WATER (AQUA), SODIUM LAURETH SULFATE, ACRYLATES COPOLYMER, TEA-LAURYL SULFATE, COCAMIDOPROPYL BETAINE, CITRIC ACID, FRAGRANCE (PARFUM), AMMONIUM CHLORIDE, DMDM HYDANTOIN, SODIUM HYDROXIDE, MENTHOL, MAGNESIUM ALUMINUM SILICATE, HYDROXYPROPYL METHYLCELLULOSE, BLUE 1 (CI

42090), RED 33 (CI 17200).

QUESTIONS OR COMMENTS?

1-877-932-7948

LABEL COPY

Maximum Medicated Dandruff Shampoo with Menthol

Drug Facts

Active ingredient	Purpose
Selenium Sulfide 1%	Anti-dandruff, Anti-seborrheic dermatitis

Uses ■ For relief of flaking and itching associated with dandruff and seborrheic dermatitis and to help prevent the chance of re-occurrence.

Warnings
For external use only.

Ask a doctor before using if you have
■ seborrheic dermatitis in areas other than the scalp.

When using this product ■ avoid contact with eyes. If product gets into eyes, rinse thoroughly with water. For use on color treated or permed hair, rinse thoroughly.

Stop using this product and ask a doctor if ■ condition worsens or does not improve after regular use of this product as directed.

Keep out of reach of children. ■ In case of accidental ingestion, get medical help or contact a Poison Control Center immediately.

Directions ■ Shake well, apply shampoo, and rinse thoroughly. For best results, use at least twice a week or as directed by a doctor.

Inactive ingredients: Water (Aqua), Sodium Laureth Sulfate, Acrylates Copolymer, TEA-Lauryl Sulfate, Cocamidopropyl Betaine, Citric Acid, Fragrance (Parfum), Ammonium Chloride, DMDM Hydantoin, Sodium Hydroxide, Menthol, Magnesium Aluminum Silicate, Hydroxypropyl Methylcellulose, Blue 1 (CI 42090), Red 33 (CI 17200).

Questions or comments? 1-877-932-7948

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EDEN PRAIRIE, MN 55344 USA. **MADE IN CANADA**
Contact us at 1-877-932-7948, or www.supervalu-ourownbrands.com

06-17367 11 FL OZ (325 mL) 06-18833 0 41163 44461 4

EQUALINE MENTHOL

selenium sulfide liquid

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:41163-620
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
SELENIUM SULFIDE (UNII: Z69D9E381Q) (SELENIUM SULFIDE - UNII:Z69D9E381Q)	SELENIUM SULFIDE	10 mg in 1 mL

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
SODIUM LAURETH SULFATE (UNII: BPV390UAP0)	
METHACRYLIC ACID - METHYL METHACRYLATE COPOLYMER (1:1) (UNII: 74G4R6TH13)	
TEA-LAURYL SULFATE (UNII: E8458C1KAA)	
COCAMIDOPROPYL BETAINE (UNII: 5OCF3O11KX)	
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	
AMMONIUM CHLORIDE (UNII: 01Q9PC255D)	
DMDM HYDANTOIN (UNII: BYR0546TOW)	
SODIUM HYDROXIDE (UNII: 55X04QC32I)	
MENTHOL (UNII: L7T10EIP3A)	
MAGNESIUM ALUMINUM SILICATE (UNII: 6M3P64V0NC)	
HYPROMELLOSES (UNII: 3NXW29V3WO)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
D&C RED NO. 33 (UNII: 9DBA0SBB0L)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:41163-620-11	325 mL in 1 BOTTLE, PLASTIC		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part358H	06/10/2013	

Labeler - SUPERVALU INC. (006961411)**Registrant** - APOLLO HEALTH AND BEAUTY CARE (201901209)**Establishment**

Name	Address	ID/FEI	Business Operations
APOLLO HEALTH AND BEAUTY CARE		201901209	manufacture(41163-620)

Revised: 6/2013

SUPERVALU INC.