

MEDICEUTICALS X-DERMA DRY SCALP AND HAIR TREATMENT- salicylic acid shampoo

Mediceutical Laboratories, Ltd.

Reference Label Set Id: c081c87b-9eb7-443b-82df-8d4dd2b51e73

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.

Mediceutical Laboratories X-Derma Dry Scalp and Hair Treatment - Drug Facts

Active Ingredient

Salicylic Acid 1.8%

Purpose

Anti-dandruff, anti-seborrheic dermatitis

Uses

Helps prevent recurrence of flaking and itching associated with dandruff and seborrheic dermatitis.

Warnings

For external use only. If condition worsens or does not improve after regular use of this product as directed, discontinue and consult a physician. If condition covers a large area of the body, consult your physician before using this product.

Keep this and all drugs out of reach of children.

If swallowed, get medical help or contact a Poison Control Center right away. Avoid contact with eyes. If contact occurs, rinse eyes thoroughly with cool water.

Directions

1. Wet hair with warm water. Distribute shampoo evenly onto scalp and hair creating a rich lather. Rinse.
2. Reapply for maximum results. Rinse. Apply Therapeutic™ Scalp and Hair Treatment Rinse working onto scalp and through the hair.
3. Thoroughly rinse.

Consult your Salon professional for additional Mediceuticals® scalp and hair treatments specifically tailored for your condition.

Inactive Ingredients

Aloe Barbadensis Leaf Juice, Apigenin, Biotin, Biotinoyl Tripeptide-1, Butylene Glycol, Butylphenyl Methyl Propional, Chamomilla Recutita (Matricaria) Flower Extract, Citric Acid, Citronellol, Cocamide DEA, Cocamidopropyl Betaine, Cucumis Sativus (Cucumber) Extract, Dimethicone, Fragrance (Parfum), Glycerin, Glycol Stearate, Helianthus Annuus (Sunflower) Seed Extract, Linalool, Methylchloroisothiazolinone, Methylisothiazolinone, Oleanic Acid, Panthenol, PEG-40 Hydrogenated

Castor Oil, PEG-150 Distearate, PPG-26-Buteth-26, Simmondsia Chinensis (Jojoba) Seed Oil, Sodium C14-16 Olefin Sulfonate, Water (Aqua)

Image of Label

MediceuticalXDermaLabel180mL.jpg



MEDICEUTICALS X-DERMA DRY SCALP AND HAIR TREATMENT

salicylic acid shampoo

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:59279-507
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
SALICYLIC ACID (UNII: O414PZ4LPZ) (SALICYLIC ACID - UNII:O414PZ4LPZ)	SALICYLIC ACID	1.8 g in 100 mL

Inactive Ingredients

Ingredient Name	Strength
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
APIGENIN (UNII: 7V515PI7F6)	
BIO TIN (UNII: 6SO6U10H04)	
BIO TINO YL TRIPEPTIDE-1 (UNII: O6380721VA)	
1-BUTENE (UNII: LY001N554L)	
BUTYLPHENYL METHYLPROPIONAL (UNII: T7540GJV69)	
CHAMOMILE (UNII: FGL3685T2X)	
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	
.BETA.-CITRONELLOL, (R)- (UNII: P01OUT964K)	
CO CO DIETHANOLAMIDE (UNII: 92005F972D)	
CO CAMIDO PROPYL BETAINE (UNII: 5OCF3O11KX)	
CUCUMBER SEED (UNII: BT3S9L53JK)	
DIMETHICONE (UNII: 92RU3N3Y1O)	
GLYCERIN (UNII: PDC6A3C0OX)	
SUNFLOWER SEED (UNII: R9N3379M4Z)	
METHYLCHLOROISOTHIAZOLINONE (UNII: DEL7T5QRPN)	
METHYLISOTHIAZOLINONE (UNII: 229D0E1QFA)	
PANTHENOL (UNII: WV9CM0O67Z)	
POLYOXYL 40 HYDROGENATED CASTOR OIL (UNII: 7YC686GQ8F)	
PEG-150 DISTEARATE (UNII: 6F36Q0I0AC)	
SIMMONDSIA CHINENSIS SEED WAX (UNII: 47X6Y9FJJ2)	
SODIUM C14-16 OLEFIN SULFONATE (UNII: O9W3D3YF5U)	
WATER (UNII: 059QF0K00R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:59279-507-06	180 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product		
2	NDC:59279-507-12	360 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product		
3	NDC:59279-507-33	1000 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part358H	11/27/2012	

Labeler - Mediceutical Laboratories, Ltd. (136770067)

Establishment

Name	Address	ID/FEI	Business Operations
Dhaliwal Laboratories, LLC		016754201	manufacture(59279-507)

Revised: 12/2015

Mediceutical Laboratories, Ltd.