

DANDRENE- pyrithione zinc shampoo
DIVINE SKIN LABORATORIES S.A. de C.V.

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.

Dandrene Anti-Dandruff Shampoo

☐ **Active ingredient**

Pyrithione zinc 2% w/w

☐ **Purpose**

Anti-dandruff

☐ **Uses**

Relieves and helps prevent recurrence of scalp itch, irritation, redness, flaking and scaling associated with dandruff.

☐ **Warnings**

☐ **For external use only.**

When using this product: Avoid☐☐ contact with eyes. If contact occurs, rinse eyes thoroughly with water.☐

☐ **Stop use 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.** ☐ If swallowed, get medical help or contact Poison Control Center right away.

☐ **Directions**

Apply shampoo to wet hair and scalp with a gentle massage, leave in for 2-3 minutes, rinse.

For best results use at least 2 times per week or as directed by a doctor.

For maximum benefit use 4-5 times a week along with Dandrene Anti-Dandruff Conditioner.

☐ **Inactive ingredients**

Water, Sodium Lauryl Sulfoacetate, Disodium Laureth Sulfosuccinate, Sodium Lauroyl Sarcosinate, Triethanolamine, Glycolic Acid, Cocamide MEA, Glyceryl Stearate, PEG-150 Distearate, Magnesium Aluminum Silicate, Sodium Citrate, Hexamidine Diisethionate, Hydrolyzed Lupine Protein, Caprylyl Glycol, Phenoxyethanol, Butylene Glycol, Pomegranate Peel (Punica Granatum) Extract, Rosemary (Rosmarinus Officinalis) Leaf Extract, Shikimic Acid, Tioxolone, Emu Oil, Fragrance, Blue 1



ANTI-DANDRUFF SHAMPOO

SHAMPOOING ANTIPELLICULAIRE

DANDRENE®

OIL CONTROL
EXFOLIATING
FAST ACTING

RÉGULATEUR DE SÉBUM
EXFOLIANT
ACTION RAPIDE

• SULFATE-FREE
SANS SULPHATE

• PARABEN-FREE
SANS PARABEN

2% PYRITHIONE ZINC
MAXIMUM STRENGTH

205 mL / 7 FL OZ e



Drug Facts

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WATER, SODIUM LAURYL SULFOACETATE, DISODIUM LAURETH SULFO SUCCINATE, SODIUM LAUROYL SARCO SINATE, TRIETHANOLAMINE, GLYCOLIC ACID, COCAMIDE MEA, GLYCERYL STEARATE, PEG-150 DISTEARATE, MAGNESIUM ALUMINUM SILICATE, SODIUM CITRATE, HEXAMIDINE DISETHIONATE, HYDROLYZED LUPINE PROTEIN, CAPRYLYL GLYCOL, PHENOXYETHANOL, BUTYLENE GLYCOL, POMEGRANATE PEEL (PUNICA GRANITUM) EXTRACT, ROSEMARY (ROSMARINUS OFFICINALIS) LEAF EXTRACT, SHIKIMIC ACID, TIOXOLONE, EMU OIL, FRAGRANCE, BLUE 1.

Produced for / Produit par: DS Healthcare Group, 200 S Biscayne Blvd., Suite 2790, Miami, FL 33131

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MADE IN USA / FABRIQUÉ AUX ÉTATS-UNIS



LB000266

DANDRENE

pyrithione zinc shampoo

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:72249-100
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
PYRITHIONE ZINC (UNII: R953O2RHZ5) (PYRITHIONE ZINC - UNII:R953O2RHZ5)	PYRITHIONE ZINC	20 mg in 1 g

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
SODIUM LAURYL SULFOACETATE (UNII: D0Y70F2B9J)	
DISODIUM LAURETH SULFO SUCCINATE (UNII: D6DH1DTN7E)	
SODIUM LAUROYL SARCO SINATE (UNII: 632GS99618)	
TROLAMINE (UNII: 9O3K93S3TK)	
GLYCOLIC ACID (UNII: 0WT12SX38S)	

COCO MONOETHANOLAMIDE (UNII: C80684146D)
GLYCERYL MONOSTEARATE (UNII: 230OU9XXE4)
PEG-150 DISTEARATE (UNII: 6F36Q0I0AC)
MAGNESIUM ALUMINUM SILICATE (UNII: 6M3P64V0NC)
SODIUM CITRATE (UNII: 1Q73Q2JULR)
HEXAMIDINE DISETHIONATE (UNII: 023XA5Z50L)
LUPINUS ALBUS SEED (UNII: 24GB753W3B)
CAPRYLYL GLYCOL (UNII: 00YIU5438U)
PHENOXYETHANOL (UNII: HIE492ZZ3T)
BUTYLENE GLYCOL (UNII: 3XUS85K0RA)
POMEGRANATE FRUIT RIND (UNII: RS999V57DU)
ROSMARINUS OFFICINALIS WHOLE (UNII: EA3289138M)
SHIKIMIC ACID (UNII: 29MS2WI2NU)
TIOXOLONE (UNII: S0FAJ1R9CD)
EMU OIL (UNII: 344821WD61)

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:72249-100-01	1 in 1 BOX	10/01/2018	
1		205 g in 1 BOTTLE; 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	05/01/2018	

Labeler - DIVINE SKIN LABORATORIES S.A. de C.V. (812464196)

Establishment

Name	Address	ID/FEI	Business Operations
A.I.G. Technologies, Inc.		086365223	manufacture(72249-100) , label(72249-100) , pack(72249-100)

Revised: 11/2020

DIVINE SKIN LABORATORIES S.A. de C.V.