

2IN1 DANDRUFF AND CONDITIONER- pyrithione zinc shampoo
Delta Kozmetik Sanayi Ve Ticaret-Selim Yesil

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

Pyrithione zinc 1%

Purpose

Anti-dandruff

Uses

• helps to treat flakes, itch, irritation, oilness or dryness caused by dandruff.

Warnings

For external use only

When using this product

•avoid contact with eyes • if contact occurs, rinse eyes with plenty of water.

Stop use and ask a doctor if

condition does not improve or worsen after regular use of this product as directed

Keep this and all drugs out of reach of children

If swallowed get medical help or contact a Poison Control Center right away.

Directions

•wet hair, •squeeze small amount into palm •lather, •rinse well

Inactive ingredients

water, sodium laureth sulfate, sodium lauryl sulfate, cocamide MEA, glycol distearate, sodium chloride, acrylates copolymer, dimethicone, zinc sulfate, fragrance, polyquaterinum-10, cetyl alcohol, triethanolamine, benzyl alcohol, methylchloroisothiazolinone, methylisothiazolinone, FDC blue no.1

Package Label



2IN1 DANDRUFF AND CONDITIONER

pyrithione zinc shampoo

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:51357-001
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
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PYRITHIONE ZINC (UNII: R953O2RHZ5) (PYRITHIONE ZINC - UNII:R953O2RHZ5)	PYRITHIONE ZINC	1 g in 100 mL
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Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
SODIUM LAURETH SULFATE (UNII: BPV390UAP0)	
SODIUM LAURYL SULFATE (UNII: 368GB5141J)	
COCO MONOETHANOLAMIDE (UNII: C80684146D)	
GLYCOL DISTEARATE (UNII: 13W7MDN21W)	
SODIUM CHLORIDE (UNII: 451W47IQ8X)	
DIMETHICONE (UNII: 92RU3N3Y1O)	
ZINC SULFATE (UNII: 89DS0H96TB)	
POLYQUATERNIUM-10 (400 CPS AT 2%) (UNII: HB1401PQFS)	
CETYL ALCOHOL (UNII: 936JST6JCN)	
TROLAMINE (UNII: 9O3K93S3TK)	
BENZYL ALCOHOL (UNII: LKG8494WBH)	
METHYLCHLOROISOTHIAZOLINONE (UNII: DEL7T5QRPN)	
METHYLISOTHIAZOLINONE (UNII: 229D0E1QFA)	
FD&C BLUE NO. 1 (UNII: HBR47K3TBD)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:51357-001-23	700 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product		
2	NDC:51357-001-14	420 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	07/15/2012	

Labeler - Delta Kozmetik Sanayi Ve Ticaret-Selim Yesil (566220234)

Establishment

Name	Address	ID/FEI	Business Operations
Delta Kozmetik Sanayi Ve Ticaret-Selim Yesil		566220234	manufacture(51357-001)

Revised: 7/2012

Delta Kozmetik Sanayi Ve Ticaret-Selim Yesil