NATURALTECH PURIFYING ANTI-DANDRUFF- pyrithione zinc gel
Davines S.p.A.

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.

NATURALTECH PURIFYING ANTI-DANDRUFF Gel

Active Ingredient

Zinc Pyrithione 0,48%

Purpose

Antidandruff

Uses

For relief of the symptoms of dandruff

Warnings

For external use only

Stop use and ask a doctor if

condition worsens or does not improve after regular use

When using this product

keep out of eyes. Rinse with water to remove.

Keep out of reach of children

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

Directions

- Spread carefully over the whole scalp, or only on areas affected by dandruff, massaging in gently.
- Leave to process for 10 minutes.
- Rinse thoroughly.
- For best results use at least twice a week or as directed by a doctor.

Other information

- you may report a serious adverse event from using this product to Report Reaction, LLC PO Box 22, Plainsboro, NJ

Inactive Ingredients

Water, Polysorbate 20, Pentasodium Pentetate, Acrylates/C10-30 Alkyl Acrylate Crosspolymer, Propylene Glycol, Glycerin, Bisabolol, Piroctone Olamine, Taraxacum Officinale (Dandelion) Root Extract, Tocopherol, Tetrasodium EDTA, Sodium Hydroxide, Linalool, Fragrance.

PRINCIPAL DISPLAY PANEL - 150 mL Bottle Carton Label

NATURALTECH™

PURIFYING ANTI-DANDRUFF GEL

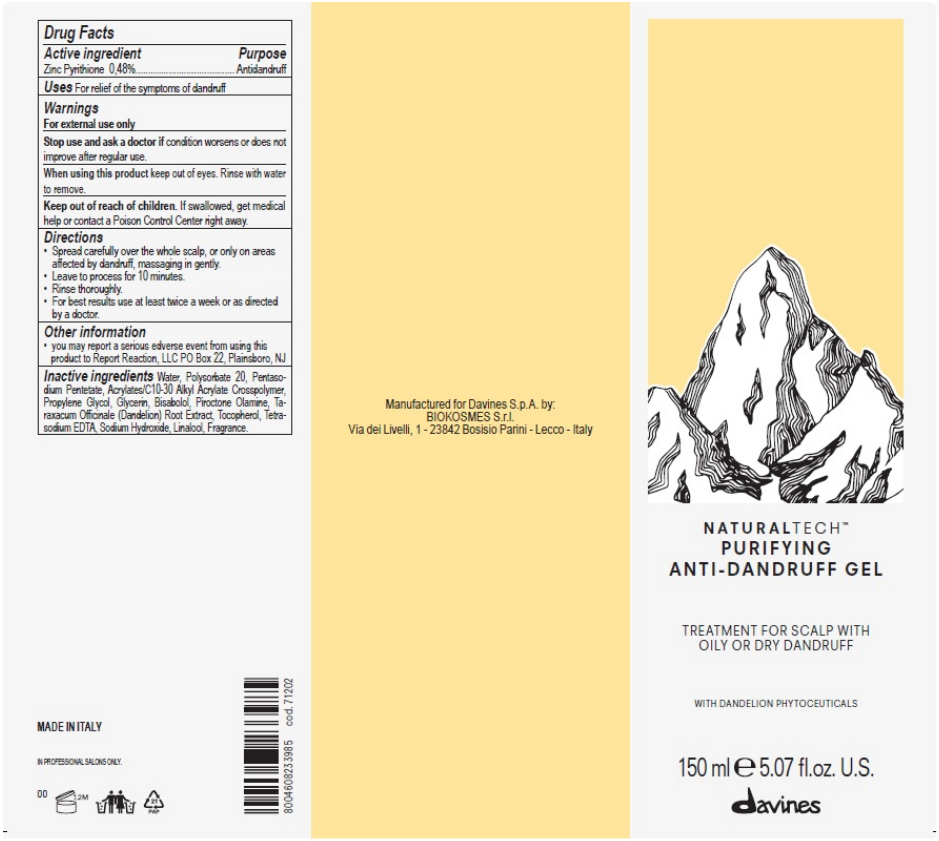
TREATMENT FOR SCALP WITH

OILY OR DRY DANDRUFF

WITH DANDELION PHYTOCEUTICALS

150 mL 5.07 Fl. Oz.

davines



NATURALTECH PURIFYING ANTI-DANDRUFF

pyrithione zinc gel

Product Information

Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:64724-1017
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
PYRITHIONE ZINC (UNII: R953O2RHZ5) (PYRITHIONE ZINC - UNII:R953O2RHZ5)	PYRITHIONE ZINC	0.48 g in 100 mL

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
POLYSORBATE 20 (UNII: 7T1F30V5YH)	
PENTASODIUM PENTETATE (UNII: 961TOZ5L7T)	
CARBOMER INTERPOLYMER TYPE A (ALLYL SUCROSE CROSSLINKED) (UNII: 59TL3WG5CO)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
GLYCERIN (UNII: PDC6A3C0OX)	
LEVOMENOL (UNII: 24WE03BX2T)	
PIROCTONE OLAMINE (UNII: A4V5C6R9FB)	
TARAXACUM OFFICINALE (UNII: 39981FM375)	
TOCOPHEROL (UNII: R0ZB2556P8)	
EDETATE SODIUM (UNII: MP1J8420LU)	
SODIUM HYDROXIDE (UNII: 55X04QC32I)	
LINALOOL, (+/-)- (UNII: D81QY6I88E)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:64724-1017-1	1 in 1 CARTON	02/29/2012	
1		150 mL 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	M032	02/29/2012	

Labeler - Davines S.p.A. (430193664)

Registrant - Davines S.p.A. (430193664)

Establishment

Name	Address	ID/FEI	Business Operations
Biokosmes SRL		436948830	manufacture(64724-1017)

Revised: 11/2022

Davines S.p.A.