

**PURESKIN ANTI DANDRUFF SHAMPOO.- pureskin anti dandruff
shampoo shampoo
Stellans Inc.**

83565-009

Active Ingredient

Ketoconazole 0.5%

Purpose

Anti Dandruff

Use

controls flaking, scaling and itching associated with dandruff

Warnings

For external use only.

Do not use

on damaged or inflamed scalp.
if you are pregnant or breast-feeding.
in children less than 12 years old.

When Using

avoid contact with eyes
if product gets into eyes, rinse thoroughly with water

Stop Use

irritation or rash occurs
condition worsens or does not improve in 2-4 weeks

Ask Doctor

- irritation or rash occurs
- condition worsens or does not improve in 2-4 weeks

Keep Out Of Reach Of Children

If swallowed, get medical help or contact a Poison Control Center (1-800-222-1222) right away.

Directions

wet hair thoroughly
apply shampoo, gently lather and massage for 2 minutes, and then rinse thoroughly.
use 2-3 times per week for up to 8 weeks or as directed by a doctor.

Other information

store at 15-25 °C

Inactive ingredients

Aqua
Glycerin
Sodium Cocoyl Isethionate
Propylene Glycol
Aloe Vera
Citric Acid
Rosemary
Tea Tree Oil
Witch Hazel
Chinese Mugwort Leaf
Licorice
Ethylhexylglycerin
Purslane
Sodium Chloride
Serine
Arginine
Coconut Oil

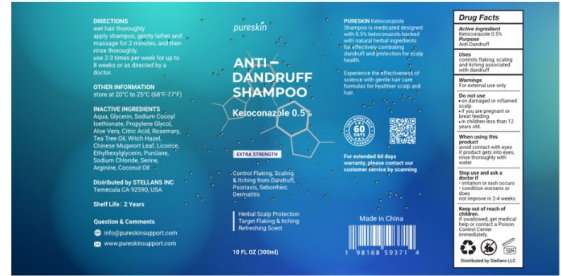
Questions

info@pureskinsupport.com
www.pureskinsupport.com

PRINCIPAL DISPLAY PANEL



62*62*165mm



PURESKIN ANTI DANDRUFF SHAMPOO.

pureskin anti dandruff shampoo shampoo

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:83565-009
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
KETOCONAZOLE (UNII: R9400W927I) (KETOCONAZOLE - UNII:R9400W927I)	KETOCONAZOLE	0.5 g in 100 mL

Inactive Ingredients

Ingredient Name	Strength

WITCH HAZEL (UNII: 101I4J0U34)
ETHYLHEXYLGLYCERIN (UNII: 147D247K3P)
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)
WATER (UNII: 059QF0KO0R)
ALOE VERA LEAF (UNII: ZY81Z83H0X)
PURSLANE (UNII: M6S840WVG5)
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)
SODIUM COCOYL ISETHIONATE (UNII: 518XTE8493)
ROSEMARY (UNII: IJ67X351P9)
ARTEMISIA ARGYI LEAF (UNII: 2JYC99Q0WZ)
COCONUT OIL (UNII: Q9L0O73W7L)
GLYCERIN (UNII: PDC6A3C0OX)
TEA TREE OIL (UNII: VIF565UC2G)
LICORICE (UNII: 61ZBX54883)
SODIUM CHLORIDE (UNII: 451W47IQ8X)
SERINE (UNII: 452VLY9402)
ARGININE (UNII: 94ZLA3W45F)

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:83565-009-01	300 mL in 1 BOTTLE; Type 0: Not a Combination Product	06/11/2024	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M032	06/11/2024	

Labeler - Stellans Inc. (111157321)

Establishment

Name	Address	ID/FEI	Business Operations
Stellans Inc.		111157321	label(83565-009) , manufacture(83565-009)

Revised: 6/2024

Stellans Inc.