FACIAL FORTRESS- pyrithione zinc shampoo Pediatric Solutions, LLC

Drug Facts

Active ingredient

Pyrithione Zinc 0.95%

Purpose

Seborrheic Dermatitis and Dandruff

Uses

Helps eliminate scalp and skin scaling, redness, flaking, itching, and irritation associated with dandruff and seborrheic dermatitis.

Warnings

For external use only.

Ask a doctor before use if you have• seborrheic dermatitis covering a large area of the body.

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 call a Poison Control Center right away.

Directions •

For best results use at least twice a week or as directed by a doctor.

• Wet hair thoroughly, massage on to scalp and skin, rinse.

Inactive ingredients

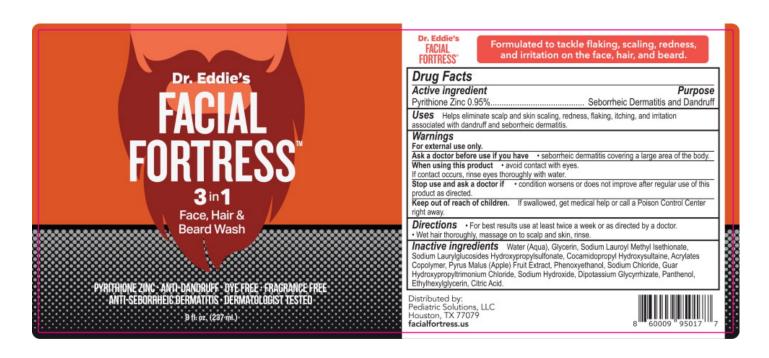
Water (Aqua), Glycerin, Sodium Lauroyl Methyl Isethionate, Sodium Laurylglucosides Hydroxypropylsulfonate, Cocamidopropyl Hydroxysultaine, Acrylates Copolymer, Pyrus Malus (Apple) Fruit Extract, Phenoxyethanol, Sodium Chloride, Guar Hydroxypropyltrimonium Chloride, Sodium Hydroxide, Dipotassium Glycyrrhizate, Panthenol, Ethylhexylglycerin, Citric Acid.

Principal Display Panel - 237 mL Bottle Label

Dr. Eddie's FACIAL FORTRESS™ 3 in 1 Face, Hair & Beard Wash

PYRITHIONE ZINC • ANTI-DANDRUFF • DYE FREE • FRAGRANCE FREE ANTI-SEBORRHEIC DERMATITIS-DERMATOLOGIST TESTED

8 fl. oz. (237 ml.)



FACIAL FORTRESS

pyrithione zinc shampoo

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PICO	Information

Product Type HUMAN OTC DRUG Item Code (Source) NDC:71566-200

Route of Administration TOPICAL

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
PYRITHIONE ZINC (UNII: R953O2RHZ5) (PYRITHIONE ZINC - UNII:R953O2RHZ5)	PYRITHIONE ZINC	0.0095 g in 1 mL

Inactive	Ingredients

Ingredient Name	Strength

WATER (UNII: 059QF0KO0R)	
GLYCERIN (UNII: PDC6A3C0OX)	
SODIUM LAUROYL METHYL ISETHIONATE (UNII: II6VCD3S6R)	
COCAMIDOPROPYL HYDROXYSULTAINE (UNII: 62V75NI93W)	
ACRYLIC ACID/ISOPHORONE DIISOCYANATE/PEG-27 COPOLYMER (UNII: R0R8I3X29J)	
APPLE (UNII: B423VGH5S9)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
SODIUM CHLORIDE (UNII: 451W47IQ8X)	
GUAR HYDROXYPROPYLTRIMONIUM CHLORIDE (1.7 SUBSTITUENTS PER SACCHARIDE) (UNII: B16G315W7A)	
SODIUM HYDROXIDE (UNII: 55X04QC32I)	
GLYCYRRHIZINATE DIPOTASSIUM (UNII: CA2Y0FE3FX)	
PANTHENOL (UNII: WV9CM0O67Z)	
ETHYLHEXYLGLYCERIN (UNII: 147D247K3P)	
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	

ı	Packaging				
	# Item C	ode	Package Description	Marketing Start Date	Marketing End Date
	1 NDC:715		1 BOTTLE, PLASTIC; Type 0: Not on Product	a 12/13/2024	

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M016	12/13/2024	

Labeler - Pediatric Solutions, LLC (080736513)

Establishment				
Name	Address	ID/FEI	Business Operations	
kdc/one Chatsworth, Inc.		118542196	manufacture(71566-200)	

Revised: 12/2024 Pediatric Solutions, LLC