

HAPPY CAPPY- pyrithione zinc shampoo
Pediatric Solutions, LLC

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 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
Happy
Cappy®**

A Pediatrician's Solution

fightes flakes

MEDICATED SHAMPOO & BODY WASH

for Seborrheic Dermatitis & Dandruff

Pyrrithione Zinc

with Licorice Root Extract to soothe redness

8 fl. oz. (237 ml.)

FRAGRANCE FREE • DYE FREE • DERMATOLOGIST TESTED

Dr. Eddie's Happy Cappy		Formulated to stop scaling and redness on a child's sensitive scalp and skin
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Distributed by:
Pediatric Solutions, LLC
Houston, TX 77079
Made in the U.S.A.
happycappysampoo.com

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HAPPY CAPPY			
pyrrithione zinc shampoo			
Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:71566-100
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
pyrithione zinc (UNII: R953O2RHZ5) (pyrithione zinc - UNII:R953O2RHZ5)	pyrithione zinc	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: WW9CM0O67Z)	
Ethylhexylglycerin (UNII: 147D247K3P)	
Citric Acid Monohydrate (UNII: 2968PHW8QP)	

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:71566-100-08	237 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	12/07/2017	
2	NDC:71566-100-11	15 mL in 1 PACKET; Type 0: Not a Combination Product	09/29/2019	

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part358H	12/07/2017	

Labeler - Pediatric Solutions, LLC (080736513)

Establishment

Name	Address	ID/FEI	Business Operations
Minimus Products LLC		022997834	PACK(71566-100)

Establishment

Name	Address	ID/FEI	Business Operations
kdc/one Chatsworth, Inc.		118542196	MANUFACTURE(71566-100)

