

PYRITHIONE ZINC- pyrithione zinc shampoo
BRANDS INTERNATIONAL

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.

Next Gen Dandruff Shampoo

For maximum dandruff control, use every time you shampoo.
Wet hair, massage unto scalp, rinse, and repeat if desired.

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

For external use only.

Water, Sodium Laureth Sulfate, Cocamidopropyl Betaine, Sodium Chloride, Glycol Distearate, Aloe vera Leaf Extract, Parfum, Vitamin E, Methylchloroisothiazolinone, Methylisothiazolinone, FD&C Blue#1 ,FD&C Red#33.

Helps prevent recurrence of flaking and itching associated with dandruff.

Keep Out of children's reach.

Anti-dandruff

Pyrithione Zinc 0.3%

Condition worsens or does not improve after regular use of this product as directed

Avoid contact with eyes. If contact occurs, rinse eyes thoroughly with water.

NextGen
SALON PROFESSIONALS

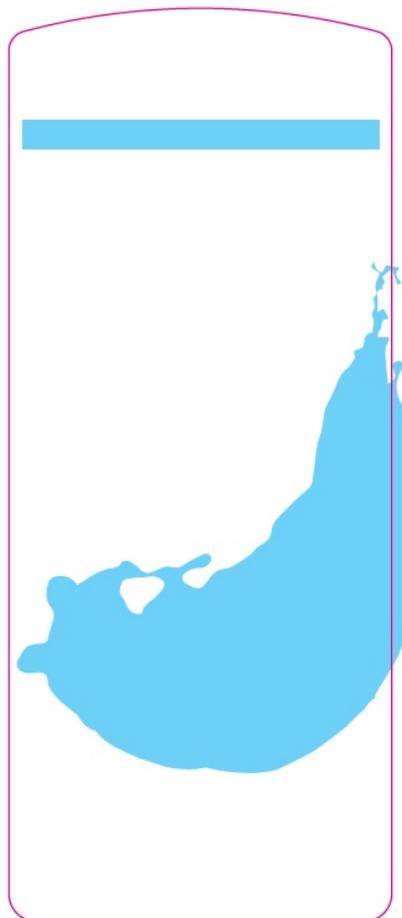
Pyrrithione Zinc
Dandruff Shampoo

Classic Clean



Helps relieve itching, dryness & light flaking

10 FL OZ (295 mL)



10 fl oz / 295 mL Dandruff Shampoo

Drug Facts

Active Ingredients.....Purpose
Pyrrithione Zinc 0.3%.....Anti-dandruff

Use helps prevent recurrence of flaking and itching associated with dandruff

Warnings
For external use only.

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 this and all drugs out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.

Directions
■ for best results use at least twice a week or as directed by a doctor, ■ for maximum dandruff control, use every time you shampoo. ■ Shake before use. ■ wet hair, massage onto scalp, rinse, repeat if desired.

Inactive Ingredients
Water, Sodium Laureth Sulfate, Cocamidopropyl Betaine, Sodium Chloride, Glycol Distearate, Fragrance, Tetrasodium EDTA, Aloe Vera Leaf Extract, Vitamin E, Methylchloroisothiazolinone, Methylisothiazolinone, FD&C Red#33 and FD&C Blue#1

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Made in Canada



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PYRITHIONE ZINC

pyrrithione zinc shampoo

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:50157-125
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
PYRITHIONE ZINC (UNII: R953O2RHZ5) (PYRITHIONE ZINC - UNII:R953O2RHZ5)	PYRITHIONE ZINC	0.3 g in 100 mL

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
SODIUM CHLORIDE (UNII: 451W47IQ8X)	
GLYCOL DISTEARATE (UNII: 13W7MDN21W)	
EDETATE SODIUM (UNII: MP1J8420LU)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	

D&C RED NO. 33 (UNII: 9DBA05BB0L)	
BASIC BLUE 1 (UNII: 92N740A24D)	
.ALPHA.-TOCOPHEROL (UNII: H4N855PNZ1)	
COCAMIDOPROPYL BETAINE (UNII: 5OCF3011KX)	
METHYLISOTHIAZOLINONE (UNII: 229D0E1QFA)	
SODIUM LAURYL SULFATE (UNII: 368GB5141J)	
METHYLCHLOROISOTHIAZOLINONE (UNII: DEL7T5QRPN)	

Product Characteristics

Color	blue	Score	
Shape		Size	
Flavor		Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:50157-125-10	295 mL in 1 BOTTLE; Type 0: Not a Combination Product	08/16/2022	
2	NDC:50157-125-35	355 mL in 1 BOTTLE; Type 0: Not a Combination Product	08/16/2022	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	M032	08/16/2022	

Labeler - BRANDS INTERNATIONAL (243748238)

Establishment

Name	Address	ID/FEI	Business Operations
BRANDS INTERNATIONAL		243748238	manufacture(50157-125)

Revised: 8/2023

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