ASSURED- pyrithione zinc shampoo Greenbrier International Inc.

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.

Assured Dandruff Shampoo

Drug Facts

Active Ingredient

Zinc Pyrithione 1%

Purpose

Anti-dandruff

Use

• helps prevent recurrence of flaking and itching associated with dandruff.

Warnings

For external use only

When using this product

• do not get into 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 as directed.

Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.

Directions

- shake well.
- wet hair.
- massage into scalp.
- rinse.
- repeat if desired.
- for best results, use at least twice a week or as directed by a doctor.
- for maximum dandruff control, use every time you shampoo.

Other information

store at 20°C (69° to 77°F)

Inactive Ingredients

Water, Sodium Laureth Sulfate, Cocamidopropyl Betaine, Sodium Lauroamphoacetate, Glycol Distearate, Sodium Chloride, Fragrance, Citric Acid, Disodium EDTA, Methylchloroisothiazolinone, Methylisothiazolinone, Blue 1, Yellow 5.

DISTRIBUTED BY

GREENBRIER INTERNATIONAL, INC.
500 VOLVO PARKWAY
CHESAPEAKE, VA 23320
MADE IN CANADA
ASSURED™

Dandruff Shampoo

Dry Scalp Care

MOISTURIZING

RELIEVES

DRYNESS • ITCHING • FLAKING

13.5 FL OZ (400 mL)



ASSURED

pyrithione zinc shampoo

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:33992-0700
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety Ingredient Name Basis of Strength PYRITHIONE ZINC (UNII: R95302RHZ5) (PYRITHIONE ZINC - UNII:R95302RHZ5) PYRITHIONE ZINC 1 g in 100 mL

Inactive Ingredients		
Ingredient Name	Strength	
WATER (UNII: 059QF0KO0R)		
SODIUM LAURETH SULFATE (UNII: BPV390UAP0)		
COCAMIDOPROPYL BETAINE (UNII: 50CF3011KX)		
SODIUM LAUROAMPHOACETATE (UNII: SLK428451L)		
GLYCOL DISTEARATE (UNII: 13W7MDN21W)		
SODIUM CHLORIDE (UNII: 451W47IQ8X)		
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)		
DISODIUM ETHYLENEDIAMINEDIACETATE (UNII: EQL53S5L0F)		
METHYLCHLOROISOTHIAZOLINONE (UNII: DEL7T5QRPN)		
METHYLISOTHIAZOLINONE (UNII: 229D0E1QFA)		
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)		
FD&C YELLOW NO. 5 (UNII: 1753WB2F1M)		

Packaging					
#	Item Code	Package Description	Marketing Start Date	Marketing End Date	
	NDC:33992- 0700-1	400 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	01/19/2017		

Marketing Information					
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date		
OTC monograph final	part358H	01/19/2017			

Labeler - Greenbrier International Inc. (610322518)

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