

DG BODY SIMPLY CLEAN- pyrrithione zinc liquid
DOLGENCORP 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.

DRUG FACTS

ACTIVE INGREDIENT

PYRITHIONE ZINC 1%

PURPOSE

ANTI-DANDRUFF

USES

TO HELP 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 OUT OF REACH OF CHILDREN

IN CASE OF ACCIDENTAL INGESTION, GET MEDICAL HELP OR CONTACT A POISON CONTROL CENTER IMMEDIATELY

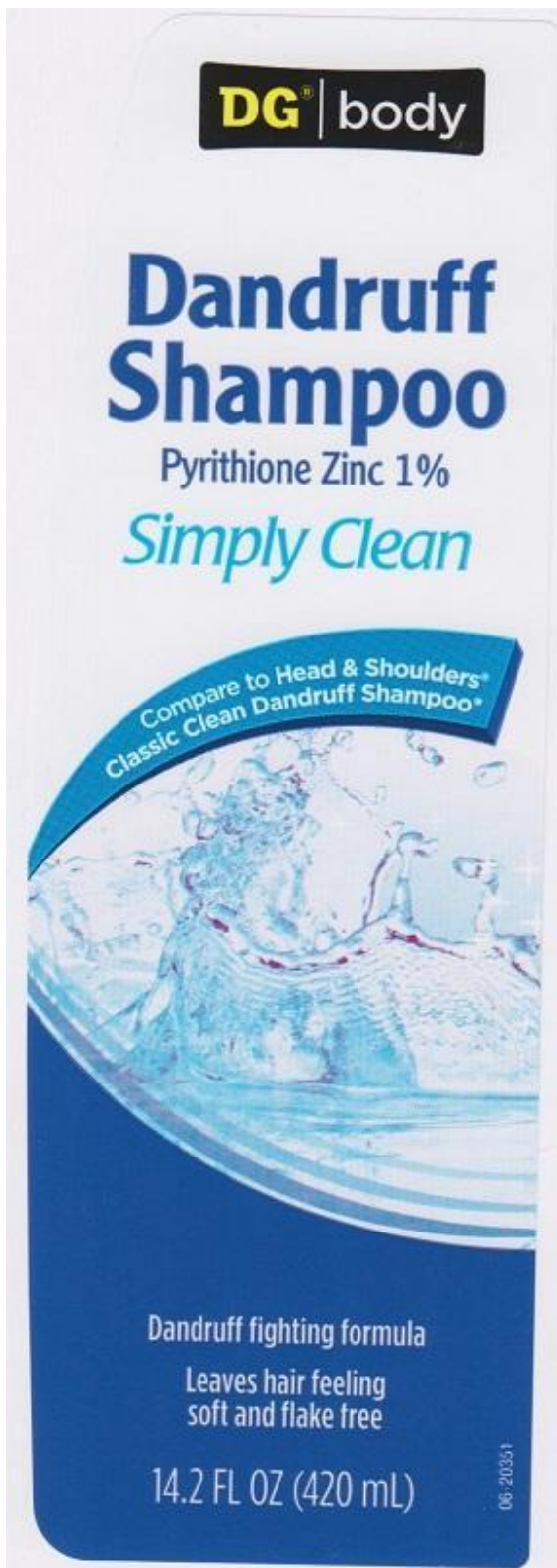
DIRECTIONS

- FOR MAXIMUM DANDRUFF CONTROL, USE EVERY TIME YOU SHAMPOO
- WET HAIR, MASSAGE ONTO SCALP AND RINSE
- REPEAT IF DESIRED

INACTIVE INGREDIENTS

WATER (AQUA), SODIUM LAURETH SULFATE, SODIUM LAURYL SULFATE, SODIUM CHLORIDE, GLYCOL DISTEARATE, ZINC CARBONATE, MAGNESIUM SULFATE, SODIUM XYLENESULFONATE, COCAMIDOPROPYL BETAINE, FRAGRANCE (PARFUM), DIMETHICONE, SODIUM BENZOATE, GUAR HYDROXYPROPYLTRIMONIUM CHLORIDE, MAGNESIUM CARBONATE HYDROXIDE, CITRIC ACID, BENZYL ALCOHOL, METHYLCHLOROISOTHIAZOLINONE, METHYLISOTHIAZOLINONE, BLUE 1 (CI 42090), RED 33 (CI 17200)

LABEL COPY



Drug Facts	
Active ingredient	Purpose
Pyrithione Zinc 1%.....	Anti-dandruff
Uses to help 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 out of reach of children. In case of accidental ingestion, get medical help or contact Poison Control Center immediately.	
Directions	
<ul style="list-style-type: none"> ■ for maximum dandruff control, use every time you shampoo ■ wet hair, massage onto scalp and rinse. ■ repeat if desired. 	
Inactive ingredients Water (Aqua), Sodium Laureth Sulfate, Sodium Lauryl Sulfate, Sodium Chloride, Glycol Distearate, Zinc Carbonate, Magnesium Sulfate, Sodium Xylenesulfonate, Cocamidopropyl Betaine, Fragrance (Parfum), Dimethicone, Sodium Benzoate, Guar Hydroxypropyltrimonium Chloride, Magnesium Carbonate Hydroxide, Citric Acid, Benzyl Alcohol, Methylchloroisothiazolinone, Methylisothiazolinone, Blue 1 (CI 42090), Red 33 (CI 17200).	

*This product is not manufactured or distributed by Procter & Gamble, the distributor of Head & Shoulders® Classic Clean pyrithione zinc Dandruff Shampoo.

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 GOODLETTSVILLE, TN 37072
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DG BODY SIMPLY CLEAN

pyrithione zinc liquid

Product Information

Product Type

HUMAN OTC DRUG

Item Code (Source)

NDC:559 10-427

Route of Administration	TOPICAL
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Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
PYRITHIONE ZINC (UNII: R953O2RHZ5) (PYRITHIONE ZINC - UNII:R953O2RHZ5)	PYRITHIONE ZINC	10 mg in 1 mL

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
SODIUM LAURETH SULFATE (UNII: BPV390UAP0)	
SODIUM LAURYL SULFATE (UNII: 368GB5141J)	
SODIUM CHLORIDE (UNII: 451W47IQ8X)	
GLYCOL DISTEARATE (UNII: 13W7MDN21W)	
ZINC CARBONATE (UNII: EQR32Y7H0M)	
MAGNESIUM SULFATE (UNII: DE08037SAB)	
SODIUM XYLENESULFONATE (UNII: G4LZF950UR)	
COCAMIDOPROPYL BETAINE (UNII: 5OCF3O11KX)	
DIMETHICONE (UNII: 92RU3N3Y1O)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	
GUAR HYDROXYPROPYLTRIMONIUM CHLORIDE (1.7 SUBSTITUENTS PER SACCHARIDE) (UNII: B16G315W7A)	
MAGNESIUM CARBONATE HYDROXIDE (UNII: YQO029V1L4)	
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	
BENZYL ALCOHOL (UNII: LKG8494WBH)	
METHYLCHLOROISOTHIAZOLINONE (UNII: DEL7T5QRPN)	
METHYLISOTHIAZOLINONE (UNII: 229D0E1QFA)	
FD&C BLUE NO. 1 (UNII: HBR47K3TBD)	
D&C RED NO. 33 (UNII: 9DBA0SBB0L)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:55910-427-14	420 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part358H	04/28/2015	

Labeler - DOLGENCORP INC (068331990)

Registrant - APOLLO HEALTH AND BEAUTY CARE (201901209)

Establishment

Name	Address	ID/FEI	Business Operations
APOLLO HEALTH AND BEAUTY CARE		201901209	manufacture(55910-427)

Revised: 4/2015

DOLGENCORP INC