PERT PLUS 2 IN 1 SHAMPOO AND CONDITIONER DRY SCALP CARE- pyrithione zinc shampoo, suspension Idelle Labs, Ltd

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.

Pert Plus 2 in 1 Shampoo & Conditioner Dry Scalp Care

Pert Plus 2 in 1 Shampoo & Conditioner Dry Scalp Care for moisturizing and relieving scalp itch Great hair should be simple Use daily: 1. Wet 2. Lather 3. Rinse. MM1

Active Ingredient

Active Ingredient

Pyrithione Zinc 1.0%

Purpose:

Anti-Dandruff

Uses

Controls the symptoms of 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. Gently massage into wet hair, lather and rinse. Repeat if desired.

Inactive Ingredients

Water, ammonium laureth sulfate, ammonium lauryl sulfate, glycol distearate, dimethicone, cetyl alcohol, cocamide MEA, sodium chloride, fragrance, guar hydroxypropyltrimonium chloride, hydrogenated polydecene, sodium citrate, sodium benzoate, polyquaternium 10, PEG-7M, trimethylolpropane tricaprylate/tricaprate, citric acid, benzyl alcohol, methylchloroisothiazolinone, methylisothiazolinone, ammonium xylene sulfonate, Yellow 10, Blue 1.

Questions or Comments?

1-800-487-7273 www.pertplus.com

Idelle Labs, Ltd. All rights reserved. Made in Canada. Distributed by Idelle Labs, Ltd., El Paso, TX 79912



label

pyrithione zinc shampoo, suspension

Product Information				
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:41595-6503	
Route of Administration	TOPICAL			

Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
PYRITHIONE ZINC (UNII: R953O2RHZ5) (PYRITHIONE ZINC - UNII:R953O2RHZ5)	PYRITHIONE ZINC	1 mL in 100 mL	

Inactive Ingredients				
Ingredient Name	Strength			
WATER (UNII: 059QF0KO0R)				
AMMO NIUM LAURETH-5 SULFATE (UNII: 43ZIH89I48)				
AMMO NIUM LAURYL SULFATE (UNII: Q7AO2R1M0B)				
GLYCOL DISTEARATE (UNII: 13W7MDN21W)				
DIMETHICO NE (UNII: 92RU3N3Y1O)				
CETYL ALCOHOL (UNII: 936JST6JCN)				
COCO MONOETHANOLAMIDE (UNII: C80684146D)				
SODIUM CHLORIDE (UNII: 451W47IQ8X)				
GUAR HYDRO XYPRO PYLTRIMO NIUM CHLO RIDE (1.7 SUBSTITUENTS PER SACCHARIDE) (UNII: B16 G315W7A)				
HYDRO GENATED POLYDECENE (550 MW) (UNII: U333RI6EB7)				
SODIUM CITRATE (UNII: 1Q73Q2JULR)				
SODIUM BENZOATE (UNII: OJ245FE5EU)				
POLYQUATERNIUM-10 (400 CPS AT 2%) (UNII: HB1401PQFS)				
POLYETHYLENE GLYCOL 7000 (UNII: Q0JET65GEL)				
TRIMETHYLOLPROPANE TRICAPRYLATE/TRICAPRATE (UNII: N1TRQ06KVJ)				
CITRIC ACID MONOHYDRATE (UNII: 2968 PHW8 QP)				
BENZYL ALCOHOL (UNII: LKG8494WBH)				
METHYLCHLOROISOTHIAZOLINONE (UNII: DEL7T5QRPN)				
METHYLISOTHIAZOLINONE (UNII: 229 D0 E1QFA)				
AMMO NIUM XYLENESULFO NATE (UNII: 4FZY6L6 XCM)				
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)				
D&C YELLOW NO. 10 (UNII: 35SW5USQ3G)				

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:41595-6503-1	400 mL in 1 BOTTLE		
2	NDC:41595-6503-2	750 mL in 1 BOTTLE		

Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
OTC MONOGRAPH FINAL	part358H	06/01/2012		

Labeler - Idelle Labs, Ltd (128822926)

Registrant - Idelle Labs, Ltd (128822926)

Establishment				
Name	Address	ID/FEI	Business Operations	
Body Blue 2006 Inc.		243094112	MANUFACTURE	

Revised: 5/2012 Idelle Labs, Ltd