AUSTRALIAN GOLD METRO 365 MEDICATED 2 IN 1 ANTI-DANDRUFF- pyrithione zinc 1% shampoo
Prime Enterprises 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.

Australian Gold Metro 365 Medicated 2 in 1 Anti - Dandruff

Active Ingredients

Pyrithione Zinc 1%

Purpose

Antidandruff

Indications

- Controls the symptoms of dandruff.
- Helps prevent recurrence of scalp itching and flaking associated with antidandruff.

Warnings

For external use only.

When using this product

- Avoid contact with the eyes. If contact occurs, rinse eyes thouroughly 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 contact a Poison Control Center right away.

Directions

- Shake well
- Wet hair, lather and massage into scalp, rinse hair thoroughly, repeat if desired.
- For best results use at least twice a week or as directed by a doctor.
- Children under 6 months of age: ask a doctor.

Acrylates Copolymer, Caprylyl Glycol, Chlorphenesin, Cocamide MEA, Cocamidopropyl Betaine, Dimethicone, Disodium EDTA, Fragrance, Glycol Stearate, Phenoxyethanol, Propylene Glycol, Sodium Hydroxide, Sodium Laureth Sulfate, Stearyl Dihydroxypropyldimonium Oligosaccharides, Water

Other Information

- Protect from heat.

Questions or Comments?

Call toll free 1-855-548-4653

Australian Gold Metro 365 Medicated 2 in 1 Anti-Dandruff

AUSTRALIAN GOLD METRO 365 MEDICATED 2 IN 1 ANTI-DANDRUFF

pyrithione zinc 1% shampoo

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:58443-0242
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
PYRITHIONE ZINC (UNII: R953O2RHZ5) (PYRITHIONE ZINC - UNII:R953O2RHZ5)	PYRITHIONE ZINC	10.32 mg in 1 mL

Inactive Ingredients	
Ingredient Name	**Strength**
CHLORPHENESIN (UNII: I670DAL4SZ)	
COCAMIDOPROPYL BETAINE (UNII: 5OCF3O11KX)	
DIMETHICONE (UNII: 92RU3N3Y1O)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	
GLYCOL STEARATE (UNII: 0324G66D0E)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
SODIUM HYDROXIDE (UNII: 55X04QC32I)	
SODIUM LAURETH SULFATE (UNII: BPV390UAP0)	
CARBOMER INTERPOLYMER TYPE A (ALLYL SUCROSE CROSSLINKED) (UNII: 59TL3WG5CO)	
CAPRYLYL GLYCOL (UNII: 00YIU5438U)	
WATER (UNII: 059QF0KO0R)	
GUAR HYDROXYPROPYLTRIMONIUM CHLORIDE (1.7 SUBSTITUENTS PER SACCHARIDE) (UNII: B16G315W7A)	
COCO MONOETHANOLAMIDE (UNII: C80684146D)	

Product Characteristics			
Color	white	**Score**	
Shape		**Size**	
Flavor		**Imprint Code**	
Contains			

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:58443-0242-5	266 mL in 1 TUBE; Type 0: Not a Combination Product	10/07/2016	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part358H	10/07/2016	

Labeler - Prime Enterprises Inc. (101946028)

Registrant - Prime Enterprises Inc. (101946028)

Establishment

Name	Address	ID/FEI	Business Operations
Prime Enterprises Inc.		101946028	manufacture(58443-0242) , label(58443-0242) , analysis(58443-0242) , pack(58443-0242)