AUSTRALIAN GOLD METRO 365 MEDICATED LEAVE-IN TREATMENT STEP 3- pyrithione zinc 0.22% cream
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 Leave In Treatment Step 3

Active Ingredients

Pyrithione Zinc 0.22%

Purpose

Antidandruff

Indications

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

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
- Use after shampooing and towel drying hair. Part hair section by section. Apply directly onto the scalp and spread using fingertips. Gently massage into scalp. Leave in.
- Apply to affected areas one to four times daily or as directed by a doctor.
- Children under 6 months of age: ask a doctor.

Caprylyl Glycol, Ceteareth-20, Cetearyl Alcohol, Cetrimonium Bromide, Cetyl Alcohol, Chlorphenesin, Disodium EDTA, Elaeis Guineensis (Palm) Oil, Fragrance, Glycerin, Phenoxyethanol, Propylene Glycol, Stearyl Dihydroxypropyldimonium Oligosaccharides, Water, may contain Citric Acid, may contain Sodium Hydroxide

Other Information

- Protect from heat.

Questions or Comments?

Call toll free 1-855-548-4653

Australian Gold Metro 365 Medicated Leave-In Treatment Step 3

AUSTRALIAN GOLD METRO 365 MEDICATED LEAVE-IN TREATMENT STEP 3

pyrithione zinc 0.22% cream

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:58443-0243
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
PYRITHIONE ZINC (UNII: R953O2RHZ5) (PYRITHIONE ZINC - UNII:R953O2RHZ5)	PYRITHIONE ZINC	2.14 mg in 1 mL

Inactive Ingredients	
Ingredient Name	Strength
CHLORPHENESIN (UNII: I670DAL4SZ)	
CETRIMONIUM BROMIDE (UNII: L64N7M9BWR)	
PALM OIL (UNII: 5QUO05548Z)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	
GLYCERIN (UNII: PDC6A3C0OX)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
SODIUM HYDROXIDE (UNII: 55X04QC32I)	
CETYL ALCOHOL (UNII: 936JST6JCN)	
POLYOXYL 20 CETOSTEARYL ETHER (UNII: YRC528SWUY)	
CAPRYLYL GLYCOL (UNII: 00YIU5438U)	
WATER (UNII: 059QF0KO0R)	
GUAR HYDROXYPROPYLTRIMONIUM CHLORIDE (1.7 SUBSTITUENTS PER SACCHARIDE) (UNII: B16G315W7A)	
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	
CETOSTEARYL ALCOHOL (UNII: 2DMT128M1S)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	

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

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:58443-0243-3	118 mL in 1 TUBE; Type 0: Not a Combination Product	10/12/2016	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part358H	10/12/2016	

Labeler - Prime Enterprises Inc. (101946028)

Registrant - Prime Enterprises Inc. (101946028)

Establishment

Name	Address	ID/FEI	Business Operations
Prime Enterprises Inc.		101946028	label(58443-0243) , manufacture(58443-0243) , analysis(58443-0243) , pack(58443-0243)

Revised: 1/2020 Prime Enterprises Inc.