AUSTRALIAN GOLD DEFENSE ZONE ANTI-DANDRUFF LEAVE-IN TREATMENT- pyrithione zinc lotion
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.

Active ingredient:

Pyrithione Zinc 0.22%

Purpose

Antidanruff

Indications:

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

Warning:

For external use only.

When using this product

- Avoid contact with the eyes. If contact occurs, rinse eyes thorougly 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.

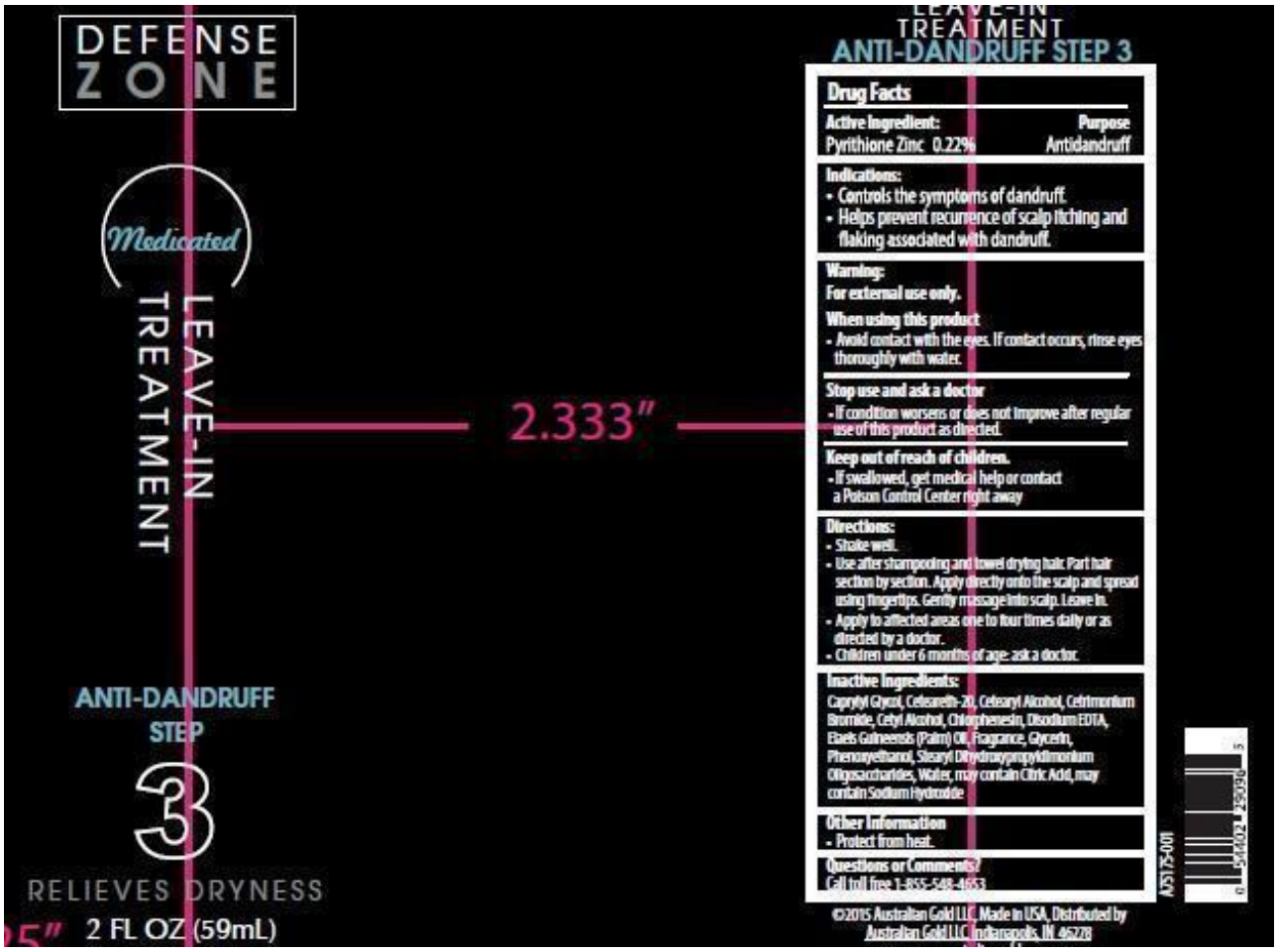
Inactive Ingrediets:

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

Questions or Comments?

Call toll free 1-855-548-4653

PRINCIPAL DISPLAY PANEL - 59 mL Bottle Label



Defense

Zone

Medicated

LEAVE-IN

TREATMENT

Anti-Dandruff

Step

3

Relieves Dryness

2 FL OZ (59mL)

AUSTRALIAN GOLD DEFENSE ZONE ANTI-DANDRUFF LEAVE-IN TREATMENT

pyrithione zinc lotion

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:58443-0186
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**
CAPRYLYL GLYCOL (UNII: 00YIU5438U)	
POLYOXYL 20 CETOSTEARYL ETHER (UNII: YRC528SWUY)	
CETOSTEARYL ALCOHOL (UNII: 2DMT128M1S)	
CETYL ALCOHOL (UNII: 936JST6JCN)	
CETRIMONIUM BROMIDE (UNII: L64N7M9BWR)	
CHLORPHENESIN (UNII: I670DAL4SZ)	
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	
PALM OIL (UNII: 5QUO05548Z)	
GLYCERIN (UNII: PDC6A3C0OX)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
SODIUM HYDROXIDE (UNII: 55X04QC32I)	
GUAR HYDROXYPROPYLTRIMONIUM CHLORIDE (1.7 SUBSTITUENTS PER SACCHARIDE) (UNII: B16G315W7A)	
WATER (UNII: 059QF0KO0R)	

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

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:58443-0186-3	59 mL in 1 BOTTLE; Type 0: Not a Combination Product	08/01/2015	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part358H	08/01/2015	

Labeler - Prime Enterprises, Inc. (101946028)

Registrant - Prime Enterprises, Inc. (101946028)

Establishment

Name	Address	ID/FEI	Business Operations
Prime Enterprises,		101946028	label(58443-0186) , pack(58443-0186) , manufacture(58443-0186) , analysis(58443-

Inc.		101946028	0186)