

**AUSTRALIAN GOLD DEFENSE ZONE ANTI-DANDRUFF STEP 2- pyrithione zinc 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.

Active ingredients

Pyrithione Zinc 1%

Purpose

Antidandruff

Uses

- For the relief of the symptoms of dandruff.
- Helps Stop 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 thoroughly with water.

Stop use and ask a doctor if

- If Condition worsens or does not improve after regular use of this product as directed

Keep out of reach of children.

- If product is 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.

Inactive Ingredients:

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

Questions or Comments?

Call toll free 1-855-548-4653

PRINCIPAL DISPLAY PANEL - 266 mL Bottle Label

PRINCIPAL DISPLAY PANEL - 59 mL Bottle Label

DEFENSE
ZONE

Medicated

2ⁱⁿ1
SHAMPOO &
CONDITIONER

ANTI-DANDRUFF
STEP
2

GRADUAL RELEASE
Provides Long Lasting Results

9 FL OZ (266mL)

2 IN 1 SHAMPOO
& CONDITIONER
ANTI-DANDRUFF STEP 2

Drug Facts

Active Ingredient:	Purpose
Pyrrithione Zinc 1%	Antidandruff

Indications:

- For the relief of the symptoms of dandruff.
- Helps stop 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 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.

- 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.

Inactive Ingredients:

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

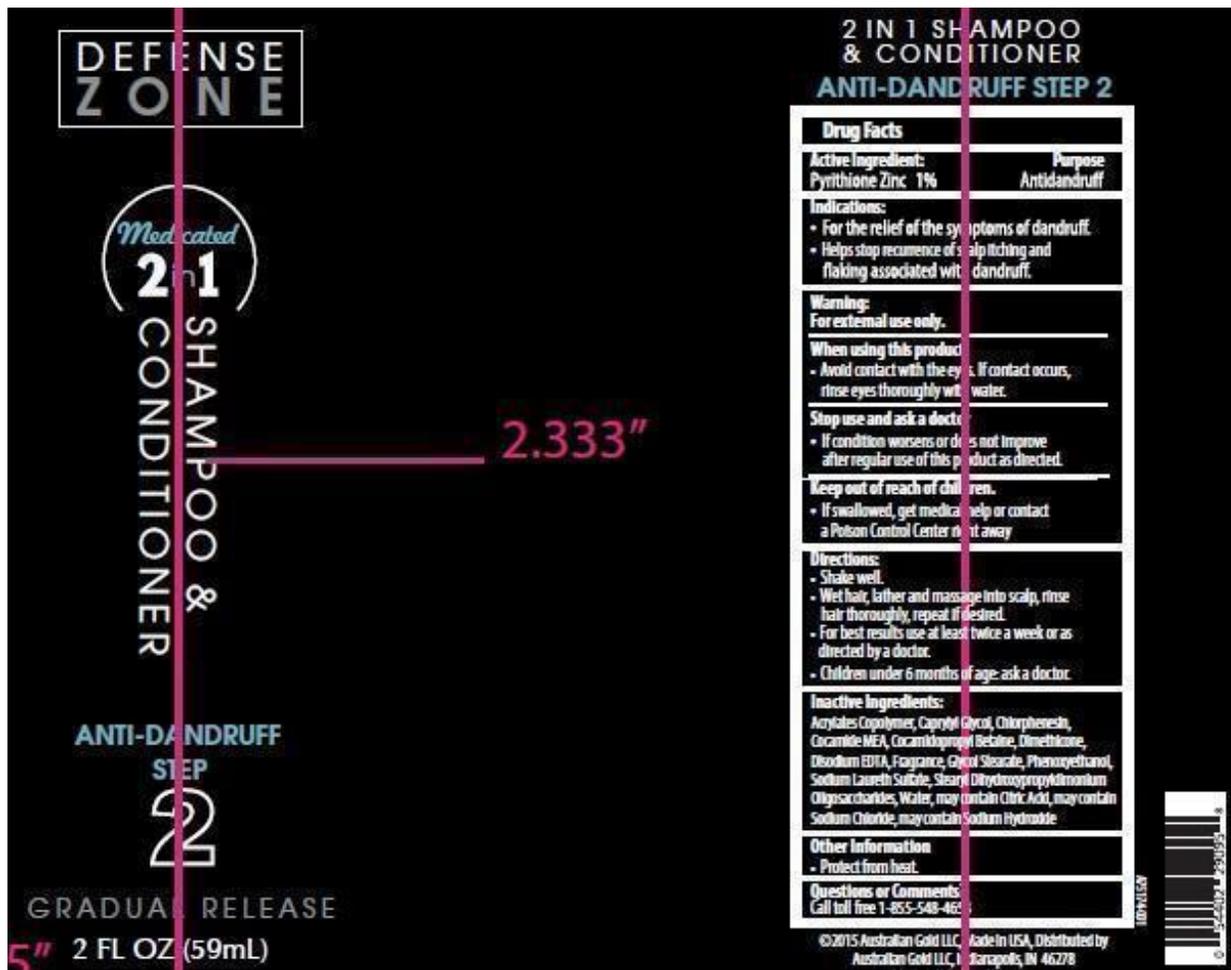
Questions or Comments?

Call toll free 1-855-548-4653

©2015 Australian Gold LLC. Made in USA. Distributed by
Australian Gold LLC, Indianapolis, IN 46278
www.australiangold.com



Defense
Zone
Medicated 2 in 1
Shampoo &
Conditioner
Anti-Dandruff
Step
2
Gradual Release
Provides Long Lasting Results
9 FL OZ (266mL)



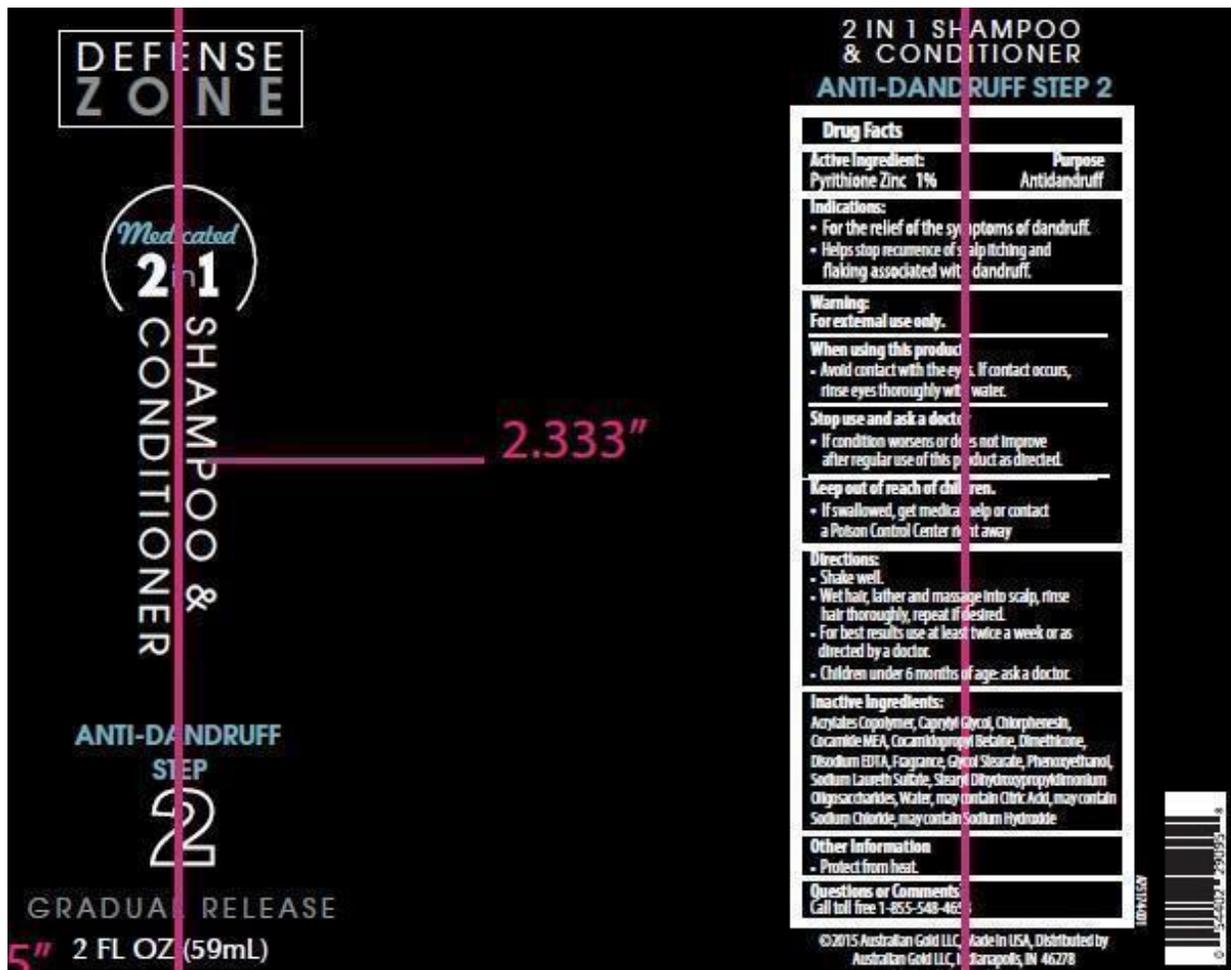
Defense
 Zone
 Medicated
 2 in 1
 Shampoo &
 Conditioner
 Anti-Dandruff
 Step
 2
 Gradual Release
 2 FL OZ (59mL)

2 IN 1 SHAMPOO
 & CONDITIONER
 ANTI-DANDRUFF STEP 2

Drug Facts	
Active Ingredient: Pyithione Zinc 1%	Purpose: Antidandruff
Indications: • For the relief of the symptoms of dandruff. • Helps stop 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 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. • 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.	
Inactive Ingredients: Acrylates Copolymer, Caprylyl Glycol, Chlorphenesin, Cocamide MEA, Cocamidopropyl Betaine, Dimethicone, Disodium EDTA, Fragrance, Glycol Stearate, Phenoxethanol, Sodium Laureth Sulfate, Stearyl Dihydroxypropyltrimonium Oligosaccharides, Water, may contain Citric Acid, may contain Sodium Chloride, may contain Sodium Hydroxide.	
Other Information • Protect from heat.	
Questions or Comments: Call toll free 1-855-548-4658.	

©2015 Australian Gold LLC. Made in USA. Distributed by
 Australian Gold LLC, Indianapolis, IN 46278





Defense
 Zone
 Medicated
 2 in 1
 Shampoo &
 Conditioner
 Anti-Dandruff
 Step
 2
 Gradual Release
 2 FL OZ (59mL)

Drug Facts	
Active Ingredient: Pyrithione Zinc 1%	Purpose: Antidandruff
Indications: • For the relief of the symptoms of dandruff. • Helps stop 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 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. • 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.	
Inactive Ingredients: Acrylates Copolymer, Caprylyl Glycol, Chlorphenesin, Cocamide MEA, Cocamidopropyl Betaine, Dimethicone, Disodium EDTA, Fragrance, Glycol Stearate, Phenoxethanol, Sodium Laureth Sulfate, Stearyl Dimethylammonium Chloride, Water, may contain Citric Acid, may contain Sodium Chloride, may contain Sodium Hydroxide.	
Other Information: • Protect from heat.	
Questions or Comments: Call toll free 1-855-548-4655	

©2015 Australian Gold LLC. Made in USA. Distributed by Australian Gold LLC, Indianapolis, IN 46278



AUSTRALIAN GOLD DEFENSE ZONE ANTI-DANDRUFF STEP 2

pyrithione zinc shampoo

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:58443-0180
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
CARBOMER INTERPOLYMER TYPE A (55000 CPS) (UNII: 59TL3WG5CO)	
CAPRYLYL GLYCOL (UNII: 00YIU5438U)	
CHLORPHENESIN (UNII: I670DAL4SZ)	
CITRIC ACID ACETATE (UNII: DSO12WL7AU)	
CO CO MONOETHANOLAMIDE (UNII: C80684146D)	
CO CAMIDOPROPYL BETAINE (UNII: 5OCF3O11KX)	
DIMETHICONE (UNII: 92RU3N3Y1O)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	
GLYCOL STEARATE (UNII: 0324G66D0E)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
SODIUM CHLORIDE (UNII: 451W47IQ8X)	
SODIUM HYDROXIDE (UNII: 55X04QC32I)	
SODIUM LAURETH SULFATE (UNII: BPV390UAP0)	
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:58443-0180-5	266 mL in 1 BOTTLE; Type 0: Not a Combination Product	06/01/2015	
2	NDC:58443-0180-3	59 mL in 1 BOTTLE; Type 0: Not a Combination Product	06/01/2015	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part358H	06/01/2015	

Labeler - Prime Enterprises, Inc. (101946028)**Registrant** - Prime Enterprises, Inc. (101946028)**Establishment**

Name	Address	ID/FEI	Business Operations
Prime Enterprises, Inc.		10 1946028	label(58443-0180) , pack(58443-0180) , manufacture(58443-0180) , analysis(58443-0180)

Revised: 1/2020

Prime Enterprises, Inc.