#### BALLVIC SEBO- pyrithione zinc shampoo INNOGENE CO.,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.

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#### **ACTIVE INGREDIENT**

Active Ingredient: Zinc Pyrithione 1.0%

### **INACTIVE INGREDIENT**

Inactive Ingredients: Water, Sodium Laureth Sulfate, Ammonium Lauryl Sulfate, Cocamidopropyl Betaine, Disodium Cocoamphodiacetate, Cocamide DEA, Dimethiconol, Glycol Distearate, Brassica Campestris (Rapeseed) Sterols, Cetearyl Alcohol, SD Alcohol 40-B, Climbazole, Glycerin, Mannitol, Propylene Glycol, Salicylic Acid, Silicone Quaternium-1, TEA-Dodecylbenzenesulfonate, Hydrolyzed Yeast Protein, Menthol, Polyquaternium-10, Ammonium Glycyrrhizate, Citric Acid, Aesculus Hippocastanum (Horse Chestnut) Seed Extract, Caffeine, Pyridoxine HCL, Allantoin, Biotin, Disodium EDTA, Guar Hydroxypropyltrimonium Chloride, Niacinamide, Panthenol, Zinc Gluconate, Acrylates/C10-30 Alkyl Acrylate Crosspolymer, Triethanolamine, Methylchloroisothiazolinone, Methylisothiazolinone

#### PURPOSE

Purpose: Antidandruff

#### WARNINGS

Warnings: 1. If the following conditions occur, you must stop using immediately. Continuous use will make the conditions worsen. Consult your dermatologist. a. Red swellings such as erythema, itchiness, or irritations. b. When directly sunlight causes the conditions mentioned above. 2. Do not apply on skin conditions such as wounds, eczema, ordermatitis. 3. Storage and Handling. a. Make sure to close the cap after use. b. Keep out of the reach of children. c. Avoid low temperature, high temperature, or direct sunlight. 4. When in eyes, wash immediately. 5. Not washing thoroughly after shampooing may cause hair loss or change in color. Make sure to wash thoroughly after use.

### **KEEP OUT OF REACH OF CHILDREN**

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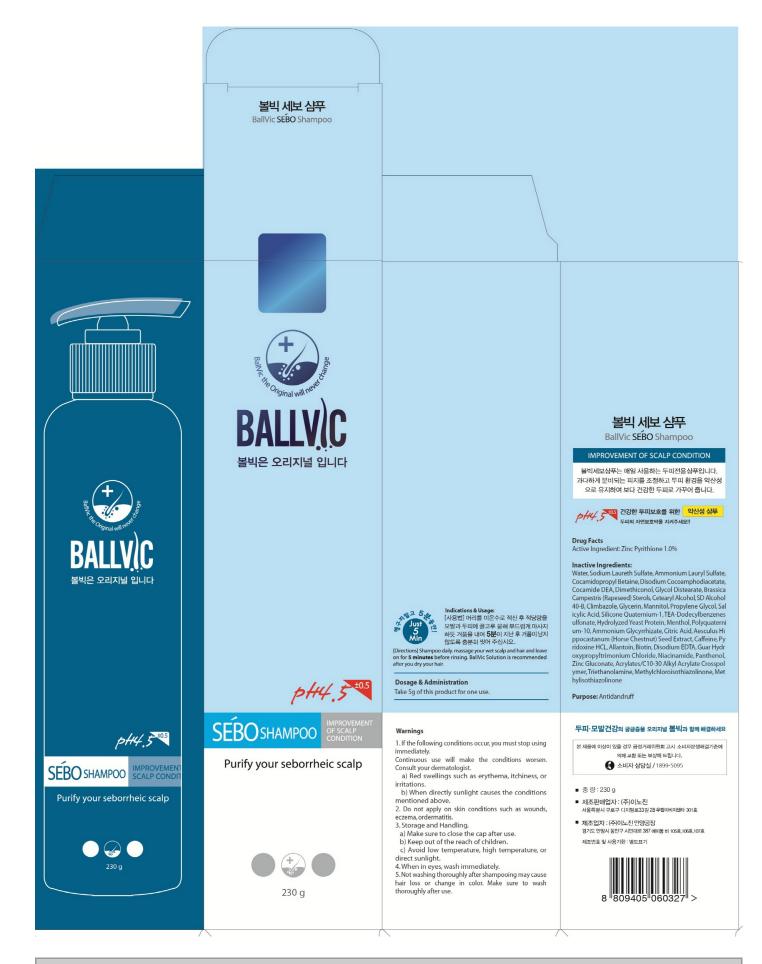
#### DIRECTIONS

Directions: Shampoo daily, massage your wel scalp and hair and leave on for 5 minutes before rinsing. BallVic Solution is recommended after you dry your hair.

#### **DOSAGE & ADMINISTRATION**

Dosage & Administration: Take 5g of this product for one use.

## PACKAGE LABEL.PRINCIPAL DISPLAY PANEL



#### **BALLVIC SEBO** pyrithione zinc shampoo

<b>Product Informati</b>	on					
Product Type		HUMAN OTC DRUG	Item Code (Source)		NDC:70540-020	
Route of Administrat	ion	TOPICAL				
Active Ingredient/	Active Moie	ety				
Ingredient Name Basis of St						Strength
<b>PYRITHIONE ZINC</b> (UNII: R95302RHZ5) (PYRITHIONE ZINC - UNII:R95302RHZ5) PYRITHIONE Z						2.3 g in 230 g
Inactive Ingredier Water (UNII: 059QF0KC Ammonium Lauryl Sul	)0R)	Ingredient Name			S	trength
Packaging						
# Item Code		Package Description		ng Start Date	Market	ing End Dat
1 NDC:70540-020-01 2	230 g in 1 CART	ON; Type 0: Not a Combination	Product			
Marketing Info	rmation					
		n Number en Meneguer h Ci	tation Markati	ng Start Date	Market	ing End Date
Marketing Category	Applicatio	n Number or Monograph Ci	Markeu	lig Start Date	Mai Keu	

# Labeler - INNOGENE CO.,LTD (688201056)

# Registrant - INNOGENE CO.,LTD (688201056)

Establishment								
Name	Address	ID/FEI	Business Operations					
INNOGENE CO.,LTD		688201056	manufacture(70540-020)					

Revised: 3/2016

#### INNOGENE CO.,LTD