MEDECEAN SEBORRHEA- 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.

ACTIVE INGREDIENT

Active Ingredient: Zinc Pyrithione 1.0%

INACTIVE INGREDIENT

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

KEEP OUT OF REACH OF CHILDREN

INDICATIONS & USAGE

Indications & Usage: 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

Just 3 Minutes



MEDECEAN SEBORRHEA

pyrithione zinc shampoo

Product Information				
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:70540-010	
Route of Administration	TOPICAL			

Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
PYRITHIONE ZINC (UNII: R953O2RHZ5) (PYRITHIONE ZINC - UNII:R953O2RHZ5)	PYRITHIONE ZINC	3.0 g in 300 g	

Inactive Ingredients			
Ingredient Name	Strength		
Water (UNII: 059QF0KO0R)			
Ammonium Lauryl Sulfate (UNII: Q7AO2R1M0B)			

l	Packaging				
ı	#	Item Code	Package Description	Marketing Start Date	Marketing End Date
ı	1 1	NDC:70540-010-01	300 g in 1 CARTON; Type 0: Not a Combination Product		

Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
OTC monograph final	part358H	02/01/2016		

Labeler - INNOGENE CO.,LTD (688201056)

Registrant - INNOGENE CO.,LTD (688201056)

Establishment				
Name	Address	ID/FEI	Business Operations	
INNOGENE CO.,LTD		688201056	manufacture(70540-010)	

Revised: 3/2016 INNOGENE CO.,LTD