

SHIKATRI CLASS- pyrithione zinc shampoo
1004LABORATORY

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 1.00%

INACTIVE INGREDIENT

Inactive Ingredients: Water, TEA-Cocoyl Glutamate, Cocamide Methyl MEA, Decyl Glucoside, Disodium Cocoamphodiacetate, Glycerin, Hydrolyzed Silk, Houttuynia Cordata Extract, Perilla Frutescens Leaf Extract, Sophora Angustifolia Root Extract, Biotin, Copper Tripeptide-1, Glycyrrhiza Glabra (Licorice) Root Extract, Pinus Sylvestris Leaf Extract, Luffa Cylindrica Fruit Extract, Acacia Concinna Fruit Extract, Lithospermum Erythrorhizon Root Extract, Camellia Sinensis Leaf Extract, Olea Europaea (Olive) Fruit Oil, Melaleuca Alternifolia (Tea Tree) Leaf Oil, Butylene Glycol, Climbazole, Panthenol, Salicylic Acid, Capsicum Annuum Fruit Extract, Polygonum Multiflorum Root Extract, Angelica Dahurica Root Extract, Rubus Idaeus (Raspberry) Fruit Extract, Angelica Gigas Root Extract, Morus Alba Bark Extract, Paeonia Albiflora Root Extract, Scutellaria Baicalensis Root Extract, Acrylates/ C10-30 Alkyl Acrylate Crosspolymer, Menthol, Citrus Aurantium Dulcis (Orange) Peel Oil, Citrus Aurantium Bergamia (Bergamot) Fruit Oil, Citrus Reticulata (Tangerine) Leaf Oil, Pelargonium Graveolens Flower Oil, Lavandula Hybrida Oil, Santalum Album (Sandalwood) Oil, Caprylyl Glycol, Caprylhydroxamic Acid, Guar Hydroxypropyltrimonium Chloride, Niacinamide, Gardenia Florida Fruit Extract

PURPOSE

Purpose: Antidandruff

WARNINGS

Warnings: 1. Stop using the product if the following problems arise while using the product as continued use could worsen the symptoms; consult with a dermatologist. A. If red spots, swelling, itchiness, and irritation occur. B. If the above problems occur on the applied area on the skin from direct sunlight 2. Do not use on areas with wounds, eczema, and dermatitis. 3. Storage and handling precautions A. Close the lid after use B. Keep away from the reach of babies and children C. Do not store in high-temperature or low-temperature and keep away from direct sunlight 4. Wash off the product if it gets in the eye 5. Inadequate cleansing after use could lead to bleaching; cleanse adequately after use

KEEP OUT OF REACH OF CHILDREN

Keep away from the reach of babies and children

INDICATIONS & USAGE

Indications & Usage: Wet the scalp and hair with warm water. Pour an appropriate amount of your hands, bubble, and massage the scalp and hair with the tip of your fingers. Cleanse cleanly with tepid water. For scalp care, we recommend shampooing twice and during the second shampoo, leave the shampoo on the hair for a minute and cleanse.

pyrithione zinc shampoo

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:69739-010
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 mg in 300 mL

Inactive Ingredients

Ingredient Name	Strength
Water (UNII: 059QF0KO0R)	
Glycerin (UNII: PDC6A3C0OX)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:69739-010-01	300 mL 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	03/01/2015	

Labeler - 1004LABORATORY (689512629)

Registrant - 1004LABORATORY (689512629)

Establishment

Name	Address	ID/FEI	Business Operations
1004LABORATORY		689512629	manufacture(69739-010)

Revised: 4/2015

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