

MOJELIM DR- pyrithione zinc shampoo
MOJELIM COSMEDI 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 ingredients: PYRITHIONE ZINC 2.0%

INACTIVE INGREDIENT

Inactive ingredients: Water, Sodium Laureth Sulfate, Cocamidopropyl Betaine, Sodium Lauryl Sulfate, Alcohol Denat, Yeast, TEA-Lauryl Sulfate, trihydroxystearin, Polyquaternium-10, Tromethamin, Parfum, Glycerin, Cocamide MEA, Tetrasodium EDTA, Panthenol, Safflower Yellow, PEG-60 Hydrogenated Castor Oil, Niacinamide, Sodium Benzoate, Sophora Angustifolia Root Extract, Paeonia Albiflora Root Extract, Tocopheryl Acetate, Salicylic Acid, PVP, Sodium Chloride, Citric Acid, Panax Ginseng Root Extract, Thuja Occidentalis Leaf Extract, Morus Alba Bark Extract, Chrysanthemum Zawadskii Extract, Lycium Chinense Fruit Extract, Acorus Gramineus Root/Stem Extract, Xanthium Strumarium Fruit Extract, Glycyrrhiza Glabra (Licorice) Root Extract, Mentha Arvensis Extract, Biotin, Glycine, Betaine, PCA, Camellia Sinensis Leaf Extract, Saccharomyces/Rice Bran Ferment, Glycine Soja (Soybean) Seed Extract, Hydrolyzed Silk, Hydrolyzed Keratin, Houttuynia Cordata Extract, Perilla Frutescens Leaf Extract, Ginkgo Biloba Leaf Extract, Panax Ginseng Root Extract, Chamaecyparis Obtusa Water, Cysteine, Camellia Japonica Seed Oil, Olea Europaea (Olive) Fruit Oil

PURPOSE

Purpose: Anti dandruff

WARNINGS

Warnings: For external use only 1. Avoid using on the following area. Scalp and skin affected by eczema. 2. Be cautious in the following case. Anyone who suffered from allergies (dermatitis due to rash, flare, itchiness, and lacquer) by drug or cosmetic 3. Consult with the doctor or pharmacist after discontinuing the use in case of symptoms, such as rash, flare and itchiness, caused by the usage of the drug. 4. General caution 1) Avoid contact with eyes. In case of contact with eyes, promptly rinse with water. In case the symptom is severe, receive treatment by an ophthalmologist. 2) Use the drug only for external use and not for internal use. 5. Caution on storage 1) Avoid direct sunlight and store in a cool place if possible. 2) Do not put in other container to maintain its quality and prevent misuse. 3) Avoid the location exposed to open flame and keep out of reach of children.

KEEP OUT OF REACH OF CHILDREN

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INDICATIONS & USAGE

Indications & Usage: □ Prevention efficacy of dandruff by keeping the hygiene of the scalp □ May have the efficacy on hair loss prevention as well as hair thickness improvement □ Hypo-allergenic on scalp with 23 types of natural components □ Containing beer yeast extracts with abundant vitamin and protein □ Enhancement of luster and elasticity by nourishing the scalp and hair

DOSAGE & ADMINISTRATION

Dosage & Administration: □ Wet the scalp and hair with warm water sufficiently. □ Put the adequate amount on the palm and make enough foam. □ Gently massage the scalp with the fingertip, and the hair with the palm for 1~3 minutes. □ Rinse the hair after 3 minutes.

PACKAGE LABEL, PRINCIPAL DISPLAY PANEL



MOJELIM DR
pyrithione zinc shampoo

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:71194-010
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
PYRITHIONE ZINC (UNII: R953O2RHZ5) (PYRITHIONE ZINC - UNII:R953O2RHZ5)	PYRITHIONE ZINC	10.0 g in 500 mL

Inactive Ingredients

Ingredient Name	Strength
Water (UNII: 059QF0K00R)	
Sodium Laureth Sulfate (UNII: BPV390UAP0)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:71194-010-02	1 in 1 CARTON	02/01/2017	
1	NDC:71194-010-01	500 mL in 1 BOTTLE, PUMP; 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	02/01/2017	

Labeler - MOJELIM COSMEDI CO., LTD (689851474)**Registrant** - MOJELIM COSMEDI CO., LTD (689851474)**Establishment**

Name	Address	ID/FEI	Business Operations
MOJELIM COSMEDI CO., LTD		689851474	relabel(71194-010)

Establishment

Name	Address	ID/FEI	Business Operations
Seoul cosmetics co.,ltd		688397660	manufacture(71194-010)