

CHEVANCE- pyrithione zinc shampoo
Yes Miracle 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 2.0%

INACTIVE INGREDIENT

Inactive Ingredients: Water, Sodium Lauroyl Sarcosinate, Cocamidopropyl Betaine, Sodium Cocoyl Glutamate, Cocamide DEA, Lauramide DEA, Coix Lacryma-Jobi Ma-yuen Seed Extract, Biotin, Niacinamide, Panthenol, Pantolactone, Glycyrrhiza Glabra (Licorice) Root Extract, Sophora Angustifolia Root Extract, Zizyphus Jujuba Fruit Extract, Angelica Keiskei Extract, Morus Alba Bark Extract, Acorus Gramineus Root/Stem Extract, Pinus Densiflora Extract, Artemisia Vulgaris Extract, Houttuynia Cordata Extract, Ginkgo Biloba Leaf Extract, Panax Ginseng Root Extract, Perilla Frutescens Leaf Extract, Camellia Sinensis Leaf Extract, Paeonia Albiflora Root Extract, Citrus Unshiu Peel Extract, Cnidium Officinale Root Extract, Polyquaternium-10, Citric Acid, Sodium Citrate, Disodium EDTA, Methylchloroisoithiazolinone, Methylisoithiazolinone, Fragrance

PURPOSE

Purpose: Scalp Protectant

WARNINGS

Warnings: Precautions for Shampoo 1.Do not use in the scalp with wound, sash, etc. 2.Side effects : If you have hypersensitivity such as rash, irritation or itching due to the use of the shampoo, please discontinue use and consult pharmacist or doctor. 3.General Precautions 1)Take care not to let it get into eyes. If it gets into the eyes, wash thoroughly with water. Get medical treatment from eye doctor if these symptoms are severe. 2)Do not use for internal use but for external use only. 4.Precautions for Storage and Handling 1)Avoid direct sunlight and keep in a less moist and cool place if possible. 2)Avoid the misuse and do not put into different containers to maintain the quality. 3)Keep away near a fire and keep out of reach of children.

KEEP OUT OF REACH OF CHILDREN

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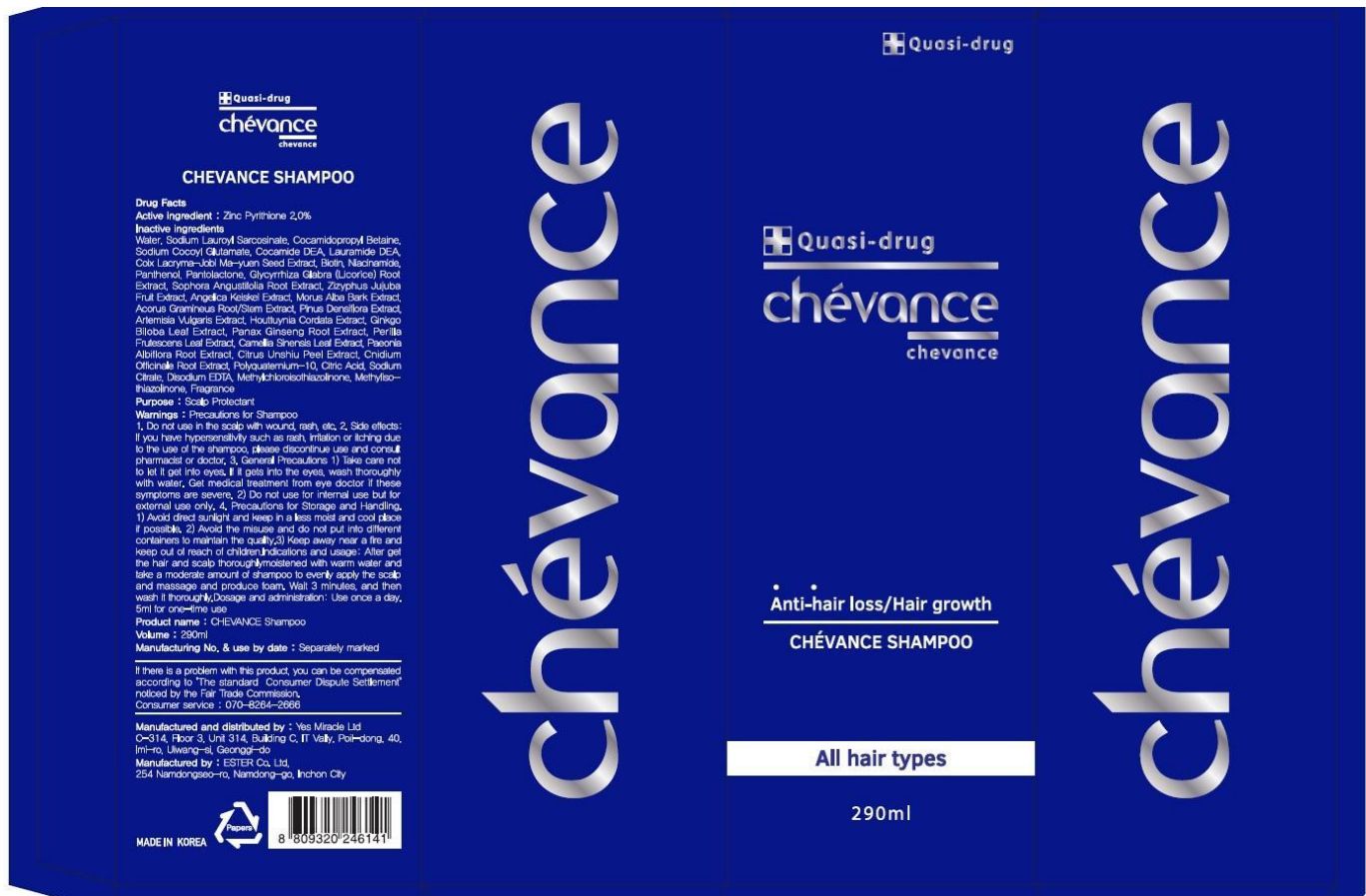
INDICATIONS & USAGE

Indications & Usage: After get the hair and scalp thoroughly moistened with warm water and take a moderate amount of shampoo to evenly apply the scalp and massage and produce foam. Wait 3 minutes, and then wash it thoroughly.

DOSAGE & ADMINISTRATION

Dosage & Administration: Use once a day. 5ml for one-time use

PACKAGE LABEL.PRINCIPAL DISPLAY PANEL



CHEVANCE

pyrithione zinc shampoo

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:70053-010
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
Pyrithione Zinc (UNII: R953O2RHZ5) (PYRITHIONE ZINC - UNII:R953O2RHZ5)	Pyrithione Zinc	5.8 mg in 290 mL

Inactive Ingredients

Ingredient Name	Strength
Water (UNII: 059QF0KO0R)	
Cocamidopropyl Betaine (UNII: 5OCF3011KX)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:70053-010-01	290 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	07/01/2015	

Labeler - Yes Miracle Ltd (689517176)

Registrant - Yes Miracle Ltd (689517176)

Establishment

Name	Address	ID/FEI	Business Operations
Yes Miracle Ltd		689517176	manufacture(70053-010)

Revised: 8/2015

Yes Miracle Ltd