

BALMERS COOLING ZONE 31 - pyrithione zinc shampoo
Tae Eul Bi 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.

Drug Facts

zinc pyrithione

water, nicotinamide, d-panthenol, biotin, l-menthol, etc.

scalp protectant

keep out or reach of the children

-Moisten hair and scalp with warm water sufficiently and massage the scalp with 3~5ml.-Apply a proper amount to foam and apply to the hair and scalp sufficiently.-Massage for about 3 minutes and rinse.

1. Do not use in the following cases(Eczema and scalp wounds)

2.Side Effects

1)Due to the use of this drug if rash, irritation, itching and symptoms of hypersensitivity occur discontinue use and consult your pharmacist or doctor

3.General Precautions

1)If in contact with the eyes, wash out thoroughly with water If the symptoms are severe, seek medical advice immediately

2)This product is for external use only. Do not use for internal use

4.Storage and handling precautions

1)If possible, avoid direct sunlight and store in cool and area of low humidity

2)In order to maintain the quality of the product and avoid misuse

3)Avoid placing the product near fire and store out in reach of children

for external use only

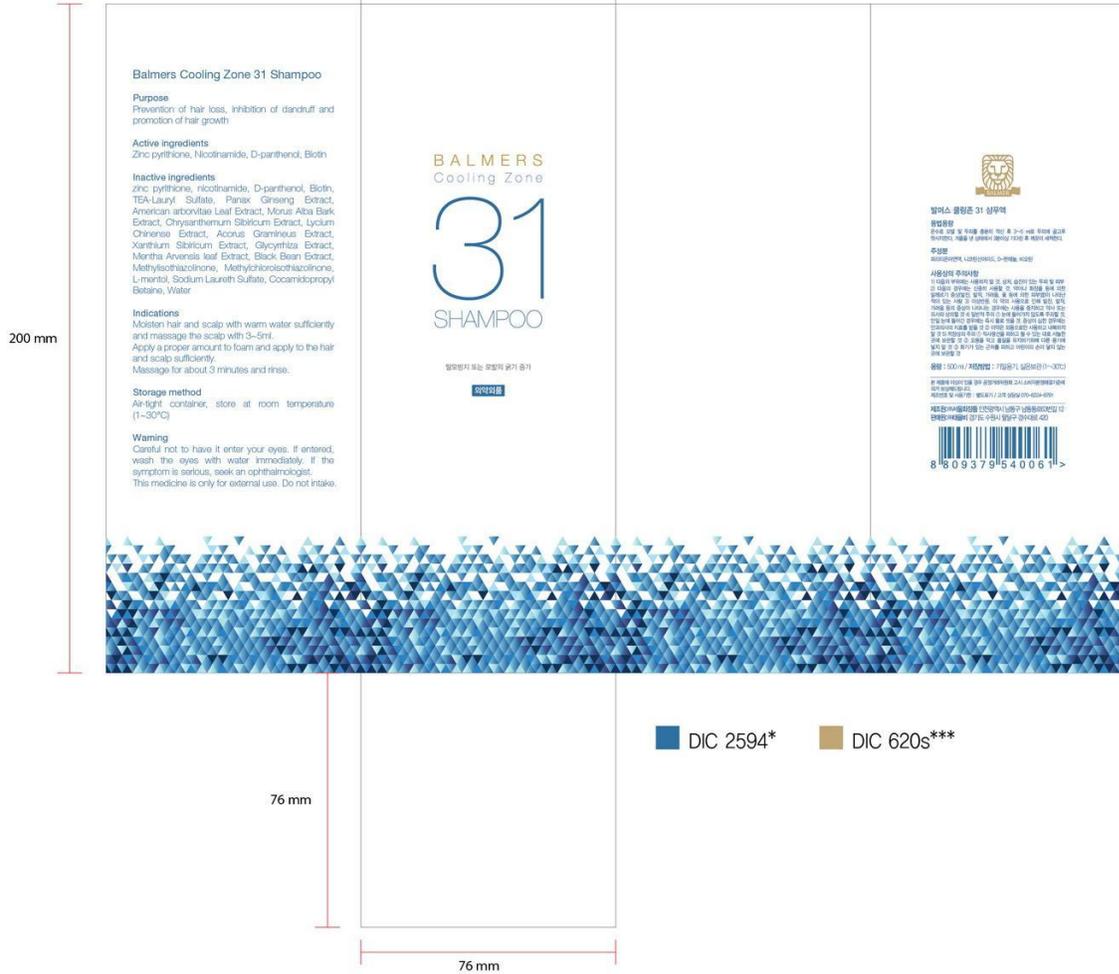
삼푸 박스

크기 : 가로 76 mm * 세로 76 mm * 높이 200 mm

컬러도수 : 6도

재질 : BV 350g (로얄아이보리) 무광코팅

삼푸 용기 크기 : 가로 72.6 mm * 세로 190 mm



BALMERS COOLING ZONE 31

pyrithione zinc shampoo

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:69927-001
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
PYRITHIONE ZINC (UNII: R953O2RHZ5) (PYRITHIONE ZINC - UNII:R953O2RHZ5)	PYRITHIONE ZINC	1.05 g in 100 mL

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
BIOTIN (UNII: 6SO6U10H04)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:69927-001-01	500 mL in 1 BOTTLE; 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	07/20/2015	

Labeler - Tae Eul Bi Co., Ltd. (689515416)**Registrant** - Tae Eul Bi Co., Ltd. (689515416)**Establishment**

Name	Address	ID/FEI	Business Operations
Tae Eul Bi Co., Ltd.		689515416	manufacture(69927-001)

Revised: 7/2015

Tae Eul Bi Co., Ltd.