

BLUE CAP- zinc pyrithione shampoo
Catalysis, SL

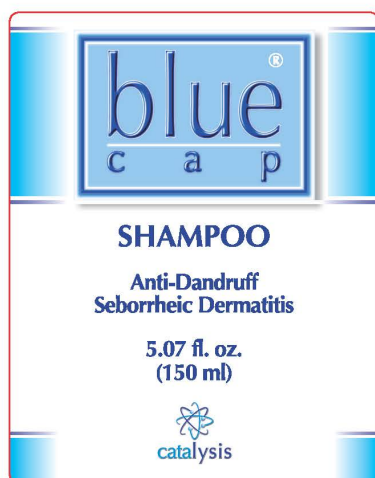
Disclaimer: Most OTC drugs are not reviewed and approved by FDA, however they may be marketed if they comply with applicable regulations and policies. FDA has not evaluated whether this product complies.

Blue Cap Shampoo

ACTIVE INGREDIENTS PURPOSE

Pyrrithione Zinc 1%..... Anti dandruff/ Seborrheic Dermatitis

Ficha Técnica / Data sheet		Diseñador / Designer: Okisam	Página / Page: 1/1
Fecha / Date: 07/06/2018	Código / Code: HBCCH150MLET Ref. SAP:	Título / Title: Etiqueta_Blue Cap _Champú_150 ml_USA_V5	
Dimensiones / Dimensions: Ancho / Width: Alto / Height: Profundo / Depth:	Tintas / Inks: ■ C ■ M ■ Y ■ K	■ P 072	Salida / Sending date:
	Material / Material:	Acabados / Finishes:	Relieve / Relief:
Observaciones / Observations:			Conforme: fecha, firma y sello / Approval: date, signature and stamp:



DRUG FACTS	
Active ingredients: Zinc Pyrithione 1%	Purpose: Anti-Dandruff Seborrheic Dermatitis
Indications: For the relief of the symptoms of dandruff and seborrheic dermatitis.	
Warnings: *For external use only. *Avoid contact with the eyes. If contact occurs, rinse eyes thoroughly with water. *If condition worsens or does not improve after regular use of this product as directed, consult with a doctor.	
When using this product: Keep out of reach of children. In case of overdose get medical help or contact a Poison Control Center immediately.	
Directions: *Wet hair. Apply a small quantity of the product into hair and massage the scalp. Rinse and repeat the application. Allow the product to act for about 5 minutes. Rinse thoroughly with enough water. *For best results use at least twice a week or as directed by the doctor.	
Other informations: Keep the product in a cool and dry place.	
<small>Inactive Ingredients: Aqua, Sodium Laureth Sulfate, Cocamidopropyl Betaine, Acrylates Copolymer, Alcohol Denat., Sodium Chloride, Methyl Glucyl Dimethacrylate, PEG/PPG-20/20 Dimethicone, Triphenyl Acetate, Sodium Hydroxide, Steareth-4, Sodium Lauryl Lactylate, Disodium EDTA, Propylene Glycol, Phenoxyethanol, Glycerin, 3-Glycerol, 4-(1-Glycerol) Glycerol, Polypropylene Glycol, Carbomer, Karsten Gum, Ethylhexylglycerin, Pentaerythrityl Tetra-2-butyl Hydroxyhydroximate, Dimethylol Urea, Sodium Benzoate, Potassium Sorbate, Methylparaben, Methylchlorophenol, Methylphenylpropane, Propylparaben, Triazopandamide, Parfum (Fragr. Citrus, Linalone, Benzyl Salicylate).</small>	
Imported by: CLINA, Inc. 3724 Crescent Court West - Whitehall, PA 18052, USA Phone: (484) 223-3500 - Fax: (484) 223-3505 E-mail: info@clina.com - www.gunsh.com	
Catalysis, S.L. Macarena, 14 + 28016 Madrid / España / Spain www.catalysis.es	Lote: Fab.: Cad.:
MADE IN SPAIN	

Warnings

- For external use only.
- Avoid contact with the eyes. If contact occurs rinse the eyes thoroughly with water
- If conditions worsens or does not improves after regular use of this product as directed, consult with a doctor
- When using this product
- KEEP out of the reach of children. In case of overdose get medical help or contact the Poison Control Center immediately.

WARNINGS

- For external use only.
- Avoid contact with the eyes. If contact occurs rinse the eyes thoroughly with water
- If conditions worsens or does not improves after regular use of this product as directed, consult with a doctor
- When using this product
- KEEP out of the reach of children. In case of overdose get medical help or contact the Poison Control Center immediately.

Warnings

Keep out of reach of children

Questions or comments?

+ 34 91 345 6902 M-F 9:00 am to 5:00 pm

Other Information

. keep the product in a cool and dry place

Directions

- Wet hair. Apply a small amount quantity of the product into hair and massage the scalp. Rinse and repeat the application. Allow the product to act for 5 minutes. Rinse thoroughly with enough water.
- For best results use at least twice a week or as directed by the doctor
- Wet hair. Apply a small amount quantity of the product into hair and massage the scalp. Rinse and repeat the application. Allow the product to act for 5 minutes. Rinse thoroughly with enough water.

- For best results use at least twice a week or as directed by the doctor

Uses

- For the relief of the symptoms of dandruff and seborrheic dermatitis

Inactive Ingredients

Water, Sodium Laureth Sulfate, Cocamidopropyl Betaine, Acrylates Copolymer, Zinc Pyrithione, Alcohol Denat, Sodium Chloride, Menthol, Glycol Distearate, PEG/PPG-20/6 Dimethicone, Tocopheryl Acetate, Sodium Hydroxide, Steareth-4, Sodium Lauroyl Lactylate, Disodium EDTA, Propylene Glycol, Phenoxyethanol, Ceramide 3, Ceramide AP, Ceramide EOP, Phytosphingosine, Cholesterol, Carbomer, Xanthan Gum, Ethylhexylglycerin, Pentaerythrityl Tetra-di-t-butyl Hydroxyhydrocinnamate, Diazolidinyl Urea, Sodium Benzoate, Potassium Sorbate, Methylchloroisothiazolinone, Methylisothiazolinone, Methylparaben, Propylparaben, Triisopropanolamine, Hexyl Cinnamal, Limonene, Benzyl Salicylate

Uses

- For the relief of the symptoms of dandruff and seborrheic dermatitis

Package Label

zinc pyrithione shampoo

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:64539-020
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 mg in 1 mL

Inactive Ingredients

Ingredient Name	Strength
PROPANEDIOL (UNII: 5965N8W85T)	
DIAZOLIDINYL UREA (UNII: H5RIZ3MPW4)	
CERAMIDE AP (UNII: F1X8L2B00J)	
WATER (UNII: 059QF0KO0R)	
SODIUM LAURYL SULFATE (UNII: 368GB5141J)	
METHACRYLIC ACID - ETHYL ACRYLATE COPOLYMER (1:2) (UNII: XRK36F13ZZ)	
SODIUM LAUROYL LACTYLATE (UNII: 7243K85WFO)	
ALCOHOL (UNII: 3K9958V90M)	
SODIUM CHLORIDE (UNII: 451W47IQ8X)	
MENTHOL (UNII: L7T10EIP3A)	
GLYCOL DISTEARATE (UNII: 13W7MDN21W)	
PEG/PPG-20/6 DIMETHICONE (UNII: PWZ7N4UIKE)	
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
SODIUM HYDROXIDE (UNII: 55X04QC32I)	
STEARETH-4 (UNII: 1VVG09S3UL)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
CARBOXYPOLYMETHYLENE (UNII: 0A5MM307FC)	
ETHYLHEXYLGLYCERIN (UNII: 147D247K3P)	
PENTAERYTHRITOL TETRAKIS(3-(3,5-DI-TERT-BUTYL-4-HYDROXYPHENYL)PROPIONATE) (UNII: 255PIF62MS)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	
POTASSIUM SORBATE (UNII: 1VPU26JZZ4)	
METHYLCHLOROISOTHIAZOLINONE (UNII: DEL7T5QRPN)	
CERAMIDE 3 (UNII: 4370DF050B)	
PHYTOSPHINGOSINE (UNII: GIN46U9Q2Q)	
CHOLESTEROL (UNII: 97C5T2UQ7J)	
XANTHAN GUM (UNII: TTV12P4NEE)	
METHYLISOTHIAZOLINONE (UNII: 229D0E1QFA)	
METHYL PARABEN (UNII: A2I8C7HI9T)	
PROPYL PARABEN (UNII: Z8IX2SC1OH)	
TRIISOPROPANOLAMINE (UNII: W9EN9DLM98)	
.ALPHA.-HEXYLCINNAMALDEHYDE (UNII: 7X6O37OK2I)	
BENZYL SALICYLATE (UNII: WAO5MKN9TU)	
LIMONENE, (+)- (UNII: GFD7C86Q1W)	

CERAMIDE 1 (UNII: 5THT33P7X7)

COCAMIDO PROPYL BETAINE (UNII: 5OCF3011KX)

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:64539-020-02	1 in 1 BOX	07/30/2018	
1	NDC:64539-020-01	150 mL in 1 TUBE; 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	07/30/2018	

Labeler - Catalysis, SL (862795119)

Registrant - Catalysis, SL (862795119)

Establishment

Name	Address	ID/FEI	Business Operations
Catalysis, SL		862795119	manufacture(64539-020)

Revised: 9/2018

Catalysis, SL