

BLUE CAP CREAM- zinc pyrithione cream
Catalysis, SL

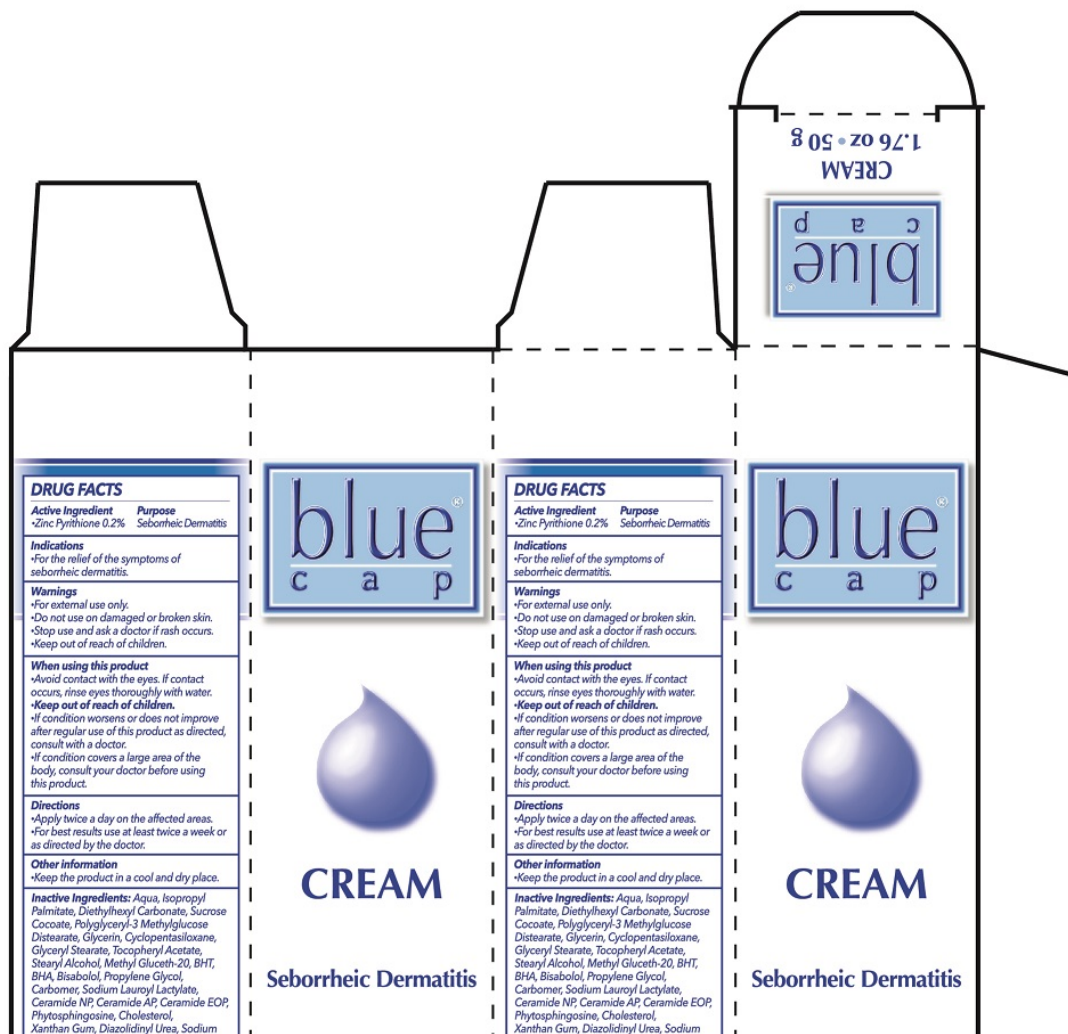
Disclaimer: Most OTC drugs are not reviewed and approved by FDA, however they may be marketed if they comply with applicable regulations and policies. FDA has not evaluated whether this product complies.

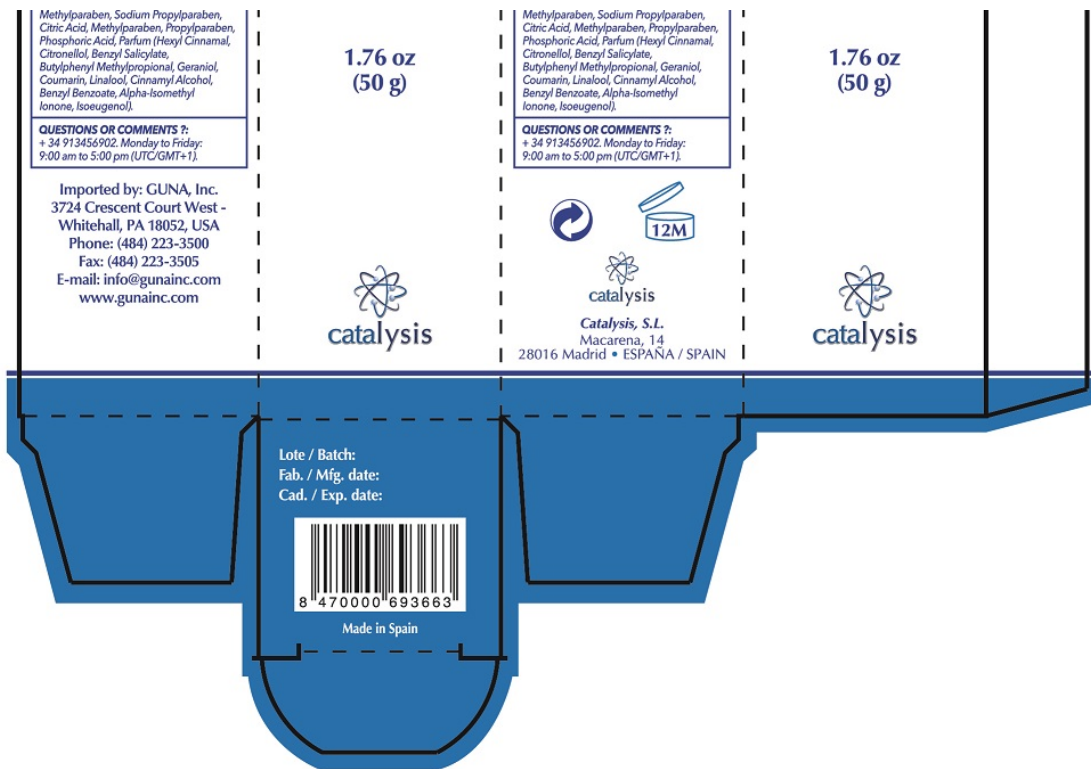
Blue Cap Cream

ACTIVE INGREDIENTS PURPOSE

Pyrrithione Zinc 0.2%..... Seborrheic Dermatitis

Ficha Técnica / Data sheet		Diseñador / Designer: Okisam	Página / Page: 1/1
Fecha / Date: 08/11/2018	Código / Code: HBCCR50GRES Ref. SAP: 022-6713	Título / Title: Caja_Blue Cap _Crema_50 g_USA_V.6	
Dimensiones / Dimensions: Ancho / Width: 36 mm Alto / Height: 163 mm Profundo / Depth: 36 mm	Tintas / Inks: C M Y K	Salida / Sending date:	
	Material / Material: 295 g	Acabados / Finishes: Plástico brillo	Relieve / Relief:
Observaciones / Observations:			Conforme: fecha, firma y sello / Approval: date, signature and stamp:





Warnings

- For external use only.
- Stop use and ask a doctor if rash occurs.
- Do not use on damaged or broken skin
- KEEP out of the reach of children

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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

- apply twice a day on affected area.
- for best results use at least twice a week or as directed by the doctor

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Uses

- For the relief of the symptoms of seborrheic dermatitis

Inactive Ingredients

Aqua, Isopropyl Palmitate, Diethylhexyl Carbonate, Sucrose Cocoate, Polyglyceryl-3 Methylglucose Distearate, Glycerin, Cyclopentasiloxane, Glyceryl Stearate. Zinc Pyrithione. Tocopheryl Acetate, Stearyl Alcohol, Methyl Gluceth-20, BHT, BHA, Propylene Glycol, Bisabolol, Carbomer, Sodium Lauroyl Lactylate, Ceramide NP, Ceramide AP, Ceramide EOP, Phytosphingosine, Cholesterol, Xanthan Gum, Diazolidinyl Urea, Sodium Methylparaben, Sodium Propylparaben, Citric Acid, Methylparaben, Propylparaben, Phosphoric Acid, Parfum

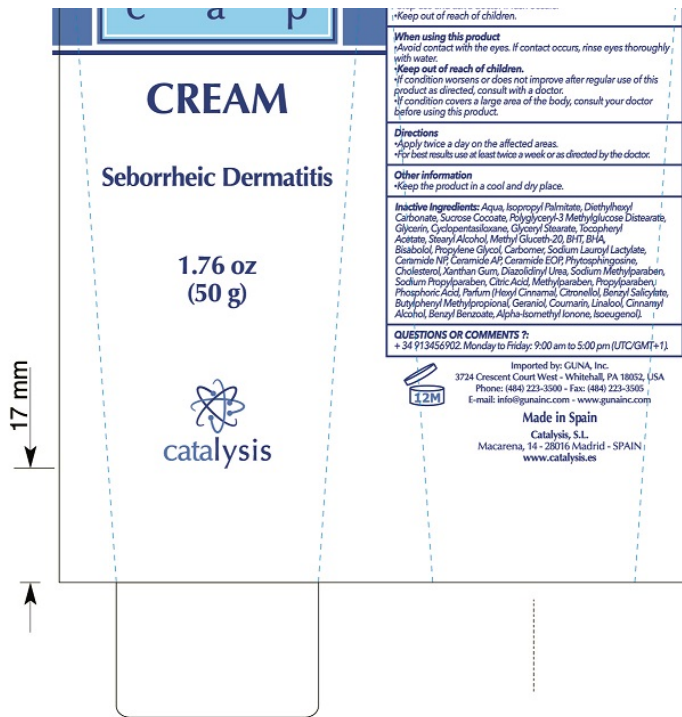
Uses

- For the relief of the symptoms of seborrheic dermatitis

Package Label

Ficha Técnica / Data sheet		Diseñador / Designer: Okisam		Página / Page: 1/1	
Fecha / Date: 08/11/2018		Código / Code: HBCCR50GTUBO Ref. SAP: 12702/03		Título / Title: Tubo_Blue Cap _Crema_50 g_USA_V.5	
Dimensiones / Dimensions: Ancho / Width: Alto / Height: Profundo / Depth:		Tintas / Inks: ■ UV1 ■ UV2 ■ UV3		Salida / Sending date:	
		Material / Material:		Acabados / Finishes:	
Relieve / Relief:		Observaciones / Observations:		Conforme: fecha, firma y sello / Approval: date, signature and stamp:	





BLUE CAP CREAM

zinc pyrithione cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:64539-022
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
PYRITHIONE ZINC (UNII: R953O2RHZ5) (PYRITHIONE ZINC - UNII:R953O2RHZ5)	PYRITHIONE ZINC	0.2 mg in 1 g

Inactive Ingredients

Ingredient Name	Strength
DIAZOLIDINYL UREA (UNII: H5RIZ3MPW4)	
CERAMIDE AP (UNII: F1X8L2B00J)	
WATER (UNII: 059QF0K00R)	
ISOPROPYL PALMITATE (UNII: 8CRQ2TH63M)	
DIETHYLHEXYL CARBONATE (UNII: YCD500Z6L)	
SODIUM LAUROYL LACTYLATE (UNII: 7243K85WFO)	
GLYCERIN (UNII: PDC6A3C0OX)	
SUCROSE COCOATE (UNII: 3H18P0UK73)	
POLYGLYCERYL-3 DISTEARATE (UNII: Z11LK470XV)	
CYCLOMETHICONE 5 (UNII: 0TH75PC10R)	
GLYCERYL MONOSTEARATE (UNII: 230OU9XXE4)	

.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)
STEARYL ALCOHOL (UNII: 2KR89I4HIY)
METHYL GLUCETH-20 (UNII: J3QD0LD11P)
LINALOOL, (-)- (UNII: 3U21E3V8I2)
BUTYLATED HYDROXYTOLUENE (UNII: 1P9D0Z171K)
BUTYLATED HYDROXYANISOLE (UNII: REK4960K2U)
PROPANEDIOL (UNII: 5965N8W85T)
GERANIOL (UNII: L837I08USY)
HYDROXYCITRONELLAL (UNII: 8SQ0VA4YUR)
LEVOMENOL (UNII: 24WE03BX2T)
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)
CARBOXYPOLYMETHYLENE (UNII: 0A5MM307FC)
CERAMIDE NP (UNII: 4370DF050B)
CERAMIDE 1 (UNII: 5THT33P7X7)
METHYL PARABEN SODIUM (UNII: CR6K9C2NHK)
PHYTOSPHINGOSINE (UNII: GIN46U9Q2Q)
CHOLESTEROL (UNII: 97C5T2UQ7J)
XANTHAN GUM (UNII: TTV12P4NEE)
PROPYL PARABEN SODIUM (UNII: 625NNB0G9N)
METHYL PARABEN (UNII: A2I8C7HI9T)
PROPYL PARABEN (UNII: Z8IX2SC1OH)
PHOSPHORIC ACID (UNII: E4GA8884NN)
.BETA.-CITRONELLOL, (S)- (UNII: 8RSY5Y5658)
BENZYL SALICYLATE (UNII: WAO5MKN9TU)
COUMARIN (UNII: A4VZ22K1WT)
BENZYL BENZOATE (UNII: N863NB338G)

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:64539-022-02	1 in 1 BOX	11/25/2018	
1	NDC:64539-022-01	1 g 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	11/25/2018	

Labeler - Catalysis, SL (862795119)

Registrant - Catalysis, SL (862795119)

Establishment

Name	Address	ID/FEI	Business Operations
Catalysis, SL		862795119	manufacture(64539-022)

