BLUE CAP CREAM- zinc pyrithione cream
Catalysis, SL

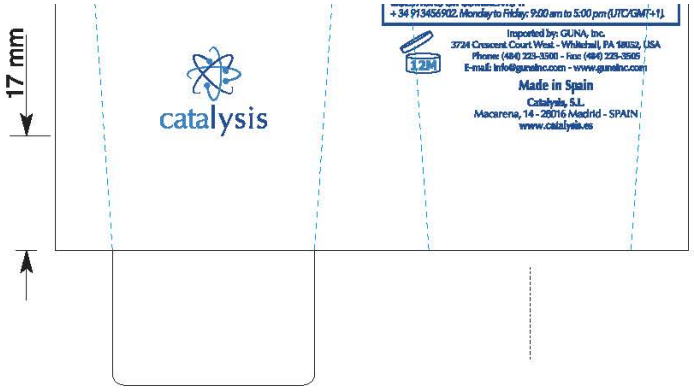
Disclaimer: Most OTC drugs are not reviewed and approved by FDA, however they may be marketed if they comply with applicable regulations and policies. FDA has not evaluated whether this product complies.

Blue Cap Cream

ACTIVE INGREDIENTS PURPOSE

Pyrithione Zinc 0.2%..... Seborrheic Dermatitis

Ficha Técnica / *Data sheet*		Diseñador / *Designer:* **Okisam**	Página / *Page:* **1/1**
Fecha / *Date:* **07/06/2018**	Código / *Code:* **HBCCR50GTUBO** Ref. SAP:	Título / *Title:* **Tubo_Blue Cap _Crema_50 g_USA_V.4**	
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:***



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 symptons 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 3, Ceramide AP, Ceramide EOP, Phytosphingosine, Cholesterol, Xanthan Gum, Diazolidinyl Urea, Sodium Methylparaben, Sodium Propylparaben, Farnesol, Citric Acid, Methylparaben, Propylparaben, Phosphoric Acid, Parfum

Uses

- For the relief of the symptons of seborrheic dermatitis

Package Label

BLUE CAP CREAM

zinc pyrithione cream

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:64539-019
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 mL

Inactive Ingredients	
Ingredient Name	**Strength**
DIAZOLIDINYL UREA (UNII: H5RIZ3MPW4)	0.24 mg in 1 mL
CERAMIDE AP (UNII: F1X8L2B00J)	0.01 mg in 1 mL
WATER (UNII: 059QF0KO0R)	63.02 mg in 1 mL
ISOPROPYL PALMITATE (UNII: 8CRQ2TH63M)	10 mg in 1 mL
DIETHYLHEXYL CARBONATE (UNII: YCD50O0Z6L)	9 mg in 1 mL
SODIUM LAUROYL LACTYLATE (UNII: 7243K85WFO)	0.2 mg in 1 mL
GLYCERIN (UNII: PDC6A3C0OX)	3 mg in 1 mL
SUCROSE COCOATE (UNII: 3H18P0UK73)	3.25 mg in 1 mL
POLYGLYCERYL-3 DISTEARATE (UNII: ZI1LK470XV)	3.2 mg in 1 mL
CYCLOMETHICONE 5 (UNII: 0THT5PCI0R)	2 mg in 1 mL
GLYCERYL MONOSTEARATE (UNII: 230OU9XXE4)	1.4 mg in 1 mL
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	0.1 mg in 1 mL
STEARYL ALCOHOL (UNII: 2KR89I4H1Y)	0.6 mg in 1 mL
METHYL GLUCETH-20 (UNII: J3QD0LD11P)	0.5 mg in 1 mL
LINALOOL, (-)- (UNII: 3U21E3V8I2)	0.1 mg in 1 mL
BUTYLATED HYDROXYTOLUENE (UNII: 1P9D0Z171K)	0.5 mg in 1 mL
BUTYLATED HYDROXYANISOLE (UNII: REK4960K2U)	0.5 mg in 1 mL
PROPANEDIOL (UNII: 5965N8W85T)	0.5 mg in 1 mL
GERANIOL (UNII: L837108USY)	0.1 mg in 1 mL
HYDROXYCITRONELLAL (UNII: 8SQ0VA4YUR)	0.1 mg in 1 mL
LEVOMENOL (UNII: 24WE03BX2T)	0.445 mg in 1 mL
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	0.05 mg in 1 mL
CARBOXYPOLYMETHYLENE (UNII: 0A5MM307FC)	0.206 mg in 1 mL
CERAMIDE 3 (UNII: 4370DF050B)	0.02 mg in 1 mL
CERAMIDE 1 (UNII: 5THT33P7X7)	0.00002 mg in 1 mL
PHYTOSPHINGOSINE (UNII: GIN46U9Q2Q)	0.01 mg in 1 mL
CHOLESTEROL (UNII: 97C5T2UQ7J)	0.01 mg in 1 mL
XANTHAN GUM (UNII: TTV12P4NEE)	0.006 mg in 1 mL
METHYLPARABEN SODIUM (UNII: CR6K9C2NHK)	0.2 mg in 1 mL
PROPYLPARABEN SODIUM (UNII: 625NNB0G9N)	0.1 mg in 1 mL
FARNESOL (UNII: EB41QIU6JL)	0.055 mg in 1 mL
METHYLPARABEN (UNII: A2I8C7HI9T)	0.094 mg in 1 mL
PROPYLPARABEN (UNII: Z8IX2SC1OH)	0.0268 mg in 1 mL
PHOSPHORIC ACID (UNII: E4GA8884NN)	0.0012 mg in 1 mL
.BETA.-CITRONELLOL, (S)- (UNII: 8RSY5Y5658)	0.1 mg in 1 mL

BENZYL SALICYLATE (UNII: WAO5MNK9TU)	0.1 mg in 1 mL
COUMARIN (UNII: A4VZ22K1WT)	0.1 mg in 1 mL
BENZYL BENZOATE (UNII: N863NB338G)	0.1 mg in 1 mL

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:64539-019-02	1 in 1 BOX	07/29/2018	
1	NDC:64539-019-01	56 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	07/29/2018	

Labeler - Catalysis, SL (862795119)

Registrant - Catalysis, SL (862795119)

Establishment

Name	Address	ID/FEI	Business Operations
Catalysis, SL		862795119	manufacture(64539-019)

Revised: 7/2018 Catalysis, SL