

**BLUE CAP- zinc pyrithione spray**  
**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 Spray**

**ACTIVE INGREDIENTS PURPOSE**

Pyrithione Zinc 0.19%..... Antidandruff/ Seborrheic Dermatitis

Ficha Técnica / Data sheet		Diseñador / Designer: <b>Okisam</b>	Página / Page: 1/1
Fecha / Date: <b>05/06/2018</b>	Código / Code: <b>HBCSP100MLTU</b> Ref. SAP:	Título / Title: <b>Tubo_Blue Cap _Spray_100ml_USA_V.4</b>	
Dimensiones / Dimensions: Ancho / Width: Alto / Height:	Tintas / Inks: ■ <b>P 072</b> ■ <b>P 285</b> ■ <b>P 2915</b> ■ <b>P 185</b> ■ <b>Negro</b>	Salida / Sending date:	
	Material / Material:	Acabados / Finishes:	Relieve / Relief:
Observaciones / Observations:			<b>Conforme: fecha, firma y sello / Approval: date, signature and stamp:</b>

**blue cap**

**SPRAY**  
**Anti-Dandruff**  
**Seborrheic Dermatitis**

**3.38 fl. oz.**  
**(100 ml)**

**catalysis**

<b>DRUG FACTS</b>	<b>Purpose:</b> Anti-Dandruff Seborrheic Dermatitis
<b>Active Ingredient:</b> Zinc Pyrithione 0.19%	
<b>Indications:</b> For the relief of the symptoms of dandruff and seborrheic dermatitis.	
<b>Warnings:</b> For external use only. Avoid contact with the eyes. If contact occurs, rinse eyes thoroughly with water. If condition persists or does not improve after regular use of this product as directed, consult with a doctor.	
<b>When using this product:</b> Keep out of reach of children. In case of overdose get medical help or contact a Poison Control Center immediately.	
<b>Directions:</b> Shake well before use. To be used in upright position. Apply 2-3 times a day to any affected areas. For best results use at least twice a week or as directed by the doctor.	
<b>Other Information:</b> Keep the product in a cool and dry place.	
<b>Inactive Ingredients:</b> Isopropyl Myristate, Alcohol Denat., Isobutane, Propene, Stearic Acid, Polysorbate 80, Tocopheryl Acetate, Butane, Formolol.	
<b>QUESTIONS OR COMMENTS? :</b> + 34 913456902. Monday to Friday: 9:00 am to 5:00 pm (UTC/GMT+1).	

Extremely flammable aerosol. Pressurized: Can explode if it's overheating. Keep away from heat, hot surfaces, sparks or other sources of ignition. Do not smoke. Do not spray on an open flame or other ignition source.  
Do not puncture or burn, even after used. Protect from direct sunlight. Do not expose to high temperatures (+30°C/122°F).  
Keep out of the reach of children. Do not breathe. Use only in a well-ventilated place.

Imported by: CAJINA, Inc. - 5724 Crescent Court West, Whitehall, PA 18627, USA - Phone: (484) 223-3300 - Fax: (484) 223-3505  
E-mail: info@ajinac.com - www.ajinac.com

Catalysis, S.L.  
Maestros, 14, 28016 Madrid.  
SPAIN. 913 456 902

100 ml (100) 3.38 fl. oz.

PELIGRO DANCER

ALTURA IMPRESIÓN BOTE CONFORMADO 82.9 mm.

**Warnings**

- For external use only.

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### **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**

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### **Uses**

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

### **Inactive Ingredients**

Isopropyl Myristate, Alcohol, Isobutane, Propane. Bisabolol, Polysorbate 80, Zinc Pyrithione, Butane, Tocopheryl Acetate, Farnesol

### **Uses**

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

### **Package Label**



**DRUG FACTS**  
 Active ingredient: **Propiconazole**  
 Also contains: **Anti-Dandruff Seborrheic Dermatitis**

**Indications:**  
 For the relief of the symptoms of dandruff and seborrheic dermatitis.

**Warnings:**  
 Do not use on the face.  
 Avoid contact with the eyes. If contact occurs, close eyes. Rinse eye with water.  
 If condition worsens or does not improve after regular use of this product for 4 weeks, consult your doctor.

**When using other products:**  
 Always use the products in combination of your doctor and medical history consult with a Pharm. Control Center immediately.

**Directions:**  
 Shake well before use. Use once in a day to dry affected area.  
 For best results use at least twice a week or as directed by the doctor.

**Other information:**  
 Keep the product in cool and dry place.

**Available in small and large quantities in:**  
 Madrid, Oviedo, Salamanca, Palencia, Zamora, Valladolid, Burgos, León, Cantabria, Asturias, Gijón, Asturias, Oviedo, Asturias, León, Cantabria, Burgos, Valladolid, Zamora, Salamanca, Palencia, Madrid.

**QUESTIONS OR COMMENTS:**  
 +34 91 546 602. Monday to Friday 10:00 am and 5:00 pm (GMT+1).

blue  
c a p



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(100 ml)



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c a p



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3.38 fl. oz.  
(100 ml)



Lot: / Batch:  
 Nbr. / Mfg. date:  
 Cod. / Exp. date:



Made in Spain

## BLUE CAP

zinc pyrithione spray

### Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:64539-021
Route of Administration	TOPICAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
PYRITHIONE ZINC (UNII: R953O2RHZ5) (PYRITHIONE ZINC - UNII:R953O2RHZ5)	PYRITHIONE ZINC	0.19 mg in 1 mL

### Inactive Ingredients

Ingredient Name	Strength
ALCOHOL (UNII: 3K9958V90M)	
FARNESOL (UNII: EB41QIU6JL)	
PROPANE (UNII: T75W991L6)	
ISOBUTANE (UNII: BXR49TP611)	
ISOPROPYL MYRISTATE (UNII: 0RE8K4LNJS)	
POLYSORBATE 80 (UNII: 6OZP39ZG8H)	
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
LEVOMENOL (UNII: 24WE03BX2T)	
BUTANE (UNII: 6LV4FOR43R)	

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:64539-021-02	1 in 1 BOX	07/31/2018	
1	NDC:64539-021-01	100 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	07/31/2018	

**Labeler** - Catalysis, SL (862795119)

**Registrant** - Catalysis, SL (862795119)

## Establishment

Name	Address	ID/FEI	Business Operations
Catalysis, SL		862795119	manufacture(64539-021)

Revised: 9/2018

Catalysis, SL