

**ZOLIDYNE- pyrithione zinc shampoo**  
**Topiderm, Inc.**

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**Zolidyne Shampoo**

***Drug Facts***

**Active ingredient**

Zinc Pyrithione, 2%

**Purpose**

Antidandruff, Seborrheic Dermatitis

**Uses**

- A gentle, specially formulated shampoo for the control of flaking and itching associated with dandruff or seborrheic dermatitis.

**Warnings**

**For external use only**

- Avoid contact with 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 a doctor
- If condition covers a large area of the body, consult your doctor before using this product
- **Keep out of reach of children.** In case of accidental ingestion, seek professional assistance or contact a Poison Control Center immediately.

**Directions**

Massage into wet scalp, lather well and rinse, leaving lather on scalp for 3-5 minutes

- For best results, use at least twice a week or as directed by your doctor.

**Inactive ingredients**

Ammonium Lauryl Sulfate, Citric Acid, Cocamidopropyl Betaine, Ethylene Glycol Distearate, FD&C Blue #1, Fragrance, Glycerin, Hydroxypropyl Methylcellulose, Lauramide MIPA, Methylchloroithiazolinone, Methylisothiazolinone, Sodium Laureth Sulfate, Water.

**PRINCIPAL DISPLAY PANEL - 200 ml Tube Label**

DERMA

TOPIX

zolidyne  
shampoo

Zinc Pyrithione, 2%

Net 6.7 fl. oz. (200 ml.)

Topix Pharmaceuticals, Inc.  
N. Amityville, NY 11701



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rev 07/16

Made in U.S.A.

203



**ZOLIDYNE**

pyrithione zinc shampoo

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:51326-203
<b>Route of Administration</b>	TOPICAL		

### Active Ingredient/Active Moiety

<b>Ingredient Name</b>	<b>Basis of Strength</b>	<b>Strength</b>
<b>PYRITHIONE ZINC</b> (UNII: R953O2RHZ5) (PYRITHIONE ZINC - UNII:R953O2RHZ5)	PYRITHIONE ZINC	20 mg in 1 mL

### Inactive Ingredients

<b>Ingredient Name</b>	<b>Strength</b>
<b>AMMONIUM LAURYL SULFATE</b> (UNII: Q7AO2R1M0B)	
<b>CITRIC ACID MONOHYDRATE</b> (UNII: 2968PHW8QP)	
<b>COCAMIDOPROPYL BETAINE</b> (UNII: 5OCF3O11KX)	
<b>GLYCOL DISTEARATE</b> (UNII: 13W7MDN21W)	
<b>FD&amp;C BLUE NO. 1</b> (UNII: H3R47K3TBD)	
<b>GLYCERIN</b> (UNII: PDC6A3C0OX)	
<b>HYPROMELLOSE, UNSPECIFIED</b> (UNII: 3NXW29V3WO)	
<b>LAURIC ISOPROPANOLAMIDE</b> (UNII: 82DUX3RRVU)	
<b>METHYLCHLOROISOTHIAZOLINONE</b> (UNII: DEL7T5QRPN)	
<b>METHYLISOTHIAZOLINONE</b> (UNII: 229D0E1QFA)	
<b>SODIUM LAURETH-3 SULFATE</b> (UNII: BPV390UAP0)	
<b>WATER</b> (UNII: 059QF0KO0R)	

### Packaging

<b>#</b>	<b>Item Code</b>	<b>Package Description</b>	<b>Marketing Start Date</b>	<b>Marketing End Date</b>
1	NDC:51326-203-67	200 mL in 1 TUBE; Type 0: Not a Combination Product	01/22/1993	

### Marketing Information

<b>Marketing Category</b>	<b>Application Number or Monograph Citation</b>	<b>Marketing Start Date</b>	<b>Marketing End Date</b>
OTC monograph drug	M032	01/22/1993	

**Labeler** - Topiderm, Inc. (049121643)

**Registrant** - Topiderm, Inc. (049121643)

**Establishment**

<b>Name</b>	<b>Address</b>	<b>ID/FEI</b>	<b>Business Operations</b>
Topiderm, Inc.		049121643	MANUFACTURE(51326-203)

## **Establishment**

<b>Name</b>	<b>Address</b>	<b>ID/FEI</b>	<b>Business Operations</b>
Topix Pharmaceuticals, Inc.		117745066	PACK(51326-203)

Revised: 11/2019

Topiderm, Inc.