## GLY-SAL 10-2 PADS- salicylic acid cloth Topiderm, Inc.

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Gly-Sal<sup>®</sup> 10-2 Pads

**Drug Facts** 

### **Active ingredient**

Salicylic Acid USP, 2%

### **Purpose**

Acne medication

#### Uses

Cleansing pads for the treatment of acne, with the skin enhancement properties of Glycolic acid.

### Warnings

- For external use only.
- Keep away from eyes, lips, and mouth.
- If irritation develops, discontinue use and consult a doctor.
- Using other topical acne medication at the same time or immediately following use of this product may increase dryness or irritation of the skin. If this occurs, only one medication should be used unless directed by a doctor.
- **Keep out of reach of children.** If swallowed, seek professional assistance or contact a Poison Control Center immediately.
- Flammable; keep tightly closed, away from flame and heat.
- Sunscreen use is recommended with any Glycolic Acid product and for an additional week thereafter, because some individuals may be more sensitive to sunlight.

### **Directions**

- Wipe the entire affected area with a moist pad one to three times daily.
- Because excessive drying of the skin can occur, start with one application daily, then gradually increase to two or three times daily if needed or as directed by a physician.
- If bothersome dryness or peeling occurs, reduce application to once a day or every other day.

### **Inactive ingredients**

Purified Water, Glycolic Acid, SD Alcohol 40B(13% v/v), Hamamelis Virginiana (Witch Hazel) Water, Ammonium Hydroxide, Polysorbate-20, Sodium Benzoate, Imidazolidinyl Urea, Acetone, Disodium EDTA.

### PRINCIPAL DISPLAY PANEL - 60 Pad Jar Label

REPLENIX® ACNE SOLUTIONS

Topix Pharmaceuticals, Inc. N. Amityville, NY 11701

Gly/Sal<sup>®</sup> 10-2 Pads

Glycolic Acid 10% Salicylic Acid USP, 2%

60 Pads



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R0519 Made in U.S.A. 712

### **GLY-SAL 10-2 PADS**

salicylic acid cloth

### **Product Information**

Product Type HUMAN OTC DRUG Item Code (Source) NDC:51326-039

Route of Administration TOPICAL

### **Active Ingredient/Active Moiety**

Ingredient Name	<b>Basis of Strength</b>	Strength
SALICYLIC ACID (UNII: O414PZ4LPZ) (SALICYLIC ACID - UNII:O414PZ4LPZ)	SALICYLIC ACID	0.02 g

### **Inactive Ingredients**

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
GLYCOLIC ACID (UNII: 0WT12SX38S)	
ALCOHOL (UNII: 3K9958V90M)	
HAMAMELIS VIRGINIANA TOP WATER (UNII: NT00Y05A2V)	
AMMONIA (UNII: 5138Q19F1X)	
POLYSORBATE 20 (UNII: 7T1F30V5YH)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	
IMIDUREA (UNII: M629807ATL)	
ACETONE (UNII: 1364PS73AF)	
EDETATE DISODIUM ANHYDROUS (UNII: 8NLQ36F6MM)	

ı	Packaging				
	#	Item Code	Package Description	Marketing Start Date	Marketing End Date
	1 NE	OC:51326-039-	60 in 1 JAR; Type 0: Not a Combination Product	07/28/2000	

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph drug	M006	07/28/2000	

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

## Registrant - Topiderm, Inc. (049121643)

Establishment				
Name	Address	ID/FEI	<b>Business Operations</b>	
Topiderm, Inc.		049121643	MANUFACTURE(51326-039)	

Establishment				
Name	Address	ID/FEI	<b>Business Operations</b>	
Topix Pharmaceuticals, Inc.		117745066	PACK(51326-039)	

Revised: 10/2019 Topiderm, Inc.