GLY-SAL 5-2 PADS- salicylic acid cloth Topiderm, Inc.

Gly-Sal[®] 5-2 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, SD Alcohol 40B (13% v/v), Glycolic Acid, Hamamelis Virginiana (Witch Hazel) Water, Polysorbate-20, Sodium Benzoate, Imidazolidinyl Urea, Ammonium Hydroxide, Acetone, Disodium EDTA.

PRINCIPAL DISPLAY PANEL - 60 Pad Jar Label

REPLENIX® ACNE SOLUTIONS

Topix Pharmaceuticals, Inc. N. Amityville, NY 11701

Gly/Sal[®] 5-2 Pads

Glycolic Acid 5% Salicylic Acid USP, 2%

60 Pads



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R0719

Made in U.S.A.

711

GLY-SAL 5-2 PADS

salicylic acid cloth

Product Information

Product Type HUMAN OTC DRUG Item Code (Source) NDC:51326-038

Route of Administration TOPICAL

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
migreateric manne	basis of strength	

SALICYLIC ACID (UNII: O414PZ4LPZ) (SALICYLIC ACID - UNII:O414PZ4LPZ) SALICYLIC ACID 0.02 g

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

F	Packaging			
#	tem Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:51326-038- 60	60 in 1 JAR; Type 0: Not a Combination Product	02/27/1990	

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph drug	M006	02/27/1990	

Labeler - Topiderm, Inc. (049121643)

Registrant - Topiderm, Inc. (049121643)

Establishment				
Name	Address	ID/FEI	Business Operations	
Topiderm, Inc.		049121643	MANUFACTURE(51326-038)	

Establishment			
Name	Address	ID/FEI	Business Operations
Topix Pharmaceuticals, Inc.		117745066	PACK(51326-038)

Revised: 10/2019 Topiderm, Inc.