REPLENIX GLY-SAL 2-2- salicylic acid liquid Topiderm, Inc.

Replenix Gly-Sal 2-2

Drug Facts

Active ingredient

Salicylic Acid USP, 2%

Purpose

Acne medication

Uses

Skin cleanser for the treatment of acne.

Warnings

For external use only

Keep away from eyes, lips, and mouth.

Using other topical medications, while using this product or immediately thereafter, may increase dryness or irritation. If this occurs discontinue use and see your doctor.

Keep out of the reach of children. If swallowed, get medical help or contact a Poison Control Center.

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

Wet affected area, apply, and rinse well.

- 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 occurs, reduce application to once a day or every other day.

Inactive ingredients

Cocamidopropyl Betaine, Disodium EDTA, Fragrance, Glycolic Acid, Linoleamidopropyl PG-Dimonium Chloride Phosphate, PEG-150 Distearate, Polysorbate-20, Propylene Glycol, Purified Water, Red #40 [CI-16035], Sodium C12-15 Pareth-15 Sulfonate, Sodium C14-16 Olefin Sulfonate, Triethanolamine, Yellow #5 [CI-19140].

PRINCIPAL DISPLAY PANEL - 200 ml Bottle Label

COMPLIMENTS OF

TOPIX PHARMACEUTICALS, INC

Gly/Sal 2-2 Pore Refining Cleanser

Glycolic Acid 2% Salicylic Acid USP, 2%

Net 6.7 fl. oz. (200 ml)

Available Custom Branded 800.445.2595 c.service@topixpharm.com

COMPLIMENTS OF		
TOPIX PHARMACEUTICALS, INC	Drug Facts Active ingredient Purpose Salicylic Acid USP, 2%Acne medication Uses Skin cleanser for the treatment of acne.	
Gly/Sal 2-2 Pore Refining Cleanser Glycolic Acid 2% Salicylic Acid USP, 2%	Uses Skin cleanser for the treatment of acne. Warnings For external use only Keep away from eyes, lips, and mouth. Using other topical medications, while using this product or immediately thereafter, may increase dryness or irritation. If this occurs discontinue use and see your doctor. Keep out of the reach of children. If swallowed, get medical help or contact a Poison Control Center. 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 Wet affected area, apply, and rinse well. ■ 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 occurs, reduce application to once a day or every other day.	
Net 6.7 fl. oz. (200 ml) Available Custom Branded 800.445.2595 c.service@topixpharm.com	Inactive ingredientsCocamidopropyl Betaine, Disodium EDTA, Fragrance, Glycolic Acid, Linoleamidopropyl PG-Dimonium Chloride Phosphate, PEG-150 Distearate, Polysorbate-20, Propylene Glycol, Purified Water, Red #40 [CI-16035], Sodium C12-15 Pareth-15 Sulfonate, Sodium C14-16 Olefin Sulfonate, Triethanolamine, Yellow #5 [CI-19140].R0619Made in U.S.A.925	

REPLENIX GLY-SAL 2-2 salicylic acid liquid						
Product Information						
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:51326-925			
Route of Administration	TOPICAL					
Active Ingredient/Active Moiety						

	Ingredient Name	Basis of Streng	th Strength				
SALICYLIC ACID (U	JNII: O414PZ4LPZ) (SALICYLIC ACID - UNII:O414PZ4	LPZ) SALICYLIC ACID	20 mg in 1 m				
Inactive Ingredients							
Ingredient Name							
COCAMIDOPROPYL BETAINE (UNII: 50CF3011KX)							
EDETATE DISODIL	JM (UNII: 7FLD91C86K)						
GLYCOLIC ACID (L	JNII: OWT12SX38S)						
LINOLEAMIDOPRO	PYL PROPYLENE GLYCOL-DIMONIUM CHLORID	E PHOSPHATE (UNII: 5Q87K	461JO)				
PEG-150 DISTEAR	ATE (UNII: 6F36Q0I0AC)						
POLYSORBATE 20	(UNII: 7T1F30V5YH)						
PROPYLENE GLYC	OL (UNII: 6DC9Q167V3)						
WATER (UNII: 059C	(FOKOOR)						
FD&C RED NO. 40	(UNII: WZB9127XOA)						
SODIUM C12-15 A	ALKETH-15 SULFONATE (UNII: 353VA59XH8)						
SODIUM C14-16 C	DLEFIN SULFONATE (UNII: 09W3D3YF5U)						
TROLAMINE (UNII: 903K93S3TK)							
FD&C YELLOW NO	D. 5 (UNII: I753WB2F1M)						
Packaging							
# Item Code	Package Description	Marketing Start M Date	larketing End Date				
1 NDC:51326-925- 01	200 mL in 1 BOTTLE; Type 0: Not a Combination Product	07/23/2019					
Marketing	Information						
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date				
OTC MONOGRAPH DRUG	M006	07/23/2019					

Labeler - Topiderm, Inc. (049121643)

Registrant - Topiderm, Inc. (049121643)

Establishment			
Name	Address	ID/FEI	Business Operations
Topiderm, Inc.		049121643	MANUFACTURE(51326-925)

Revised: 7/2024

Topiderm, Inc.