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

Replenix® Acne Solutions Gly-Sal® 2-2 Foaming Cleanser

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

Water, Sodium Lauroyl Sarcosinate, Sodium Methyl Cocoyl Taurate, PEG-7 Glyceryl Cocoate, Disodium Cocoamphodiacetate, Potassium Hydroxide, Glycolic Acid, Green Tea Extract, Cucumber Extract, Zinc PCA, Copper PCA, Willow Bark Extract, Hydroxyethylcellulose, Phenoxyethanol, Disodium EDTA.

PRINCIPAL DISPLAY PANEL - 200 ml Bottle Label

REPLENiX®
ACNE SOLUTIONS

Gly/Sal® 2-2
Foaming
Cleanser

Glycolic Acid 2%
Salicylic Acid USP, 2%

Net 6.7 fl. oz. (200 ml)

Topix Pharmaceuticals, Inc.
N. Amityville, NY 11701

REPLENIX ACNE GLY-SAL 2-2 FOAMING CLEANSER

salicylic acid liquid

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:51326-929
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
SALICYLIC ACID (UNII: O414PZ4LPZ) (SALICYLIC ACID - UNII:O414PZ4LPZ)	SALICYLIC ACID	20 mg in 1 mL

Inactive Ingredients	
Ingredient Name	**Strength**
WATER (UNII: 059QF0KO0R)	
SODIUM LAUROYL SARCOSINATE (UNII: 632GS99618)	
SODIUM METHYL COCOYL TAURATE (UNII: JVL98CG53G)	
PEG-7 GLYCERYL COCOATE (UNII: VNX7251543)	
DISODIUM COCOAMPHODIACETATE (UNII: 18L9G3U51M)	
POTASSIUM HYDROXIDE (UNII: WZH3C48M4T)	
GLYCOLIC ACID (UNII: 0WT12SX38S)	
GREEN TEA LEAF (UNII: W2ZU1RY8B0)	
CUCUMBER (UNII: YY7C30VXJT)	
ZINC PIDOLATE (UNII: C32PQ86DH4)	
COPPER PIDOLATE (UNII: 497G7G1SL1)	
WILLOW BARK (UNII: S883J9JDYX)	
HYDROXYETHYL CELLULOSE (100 MPA.S AT 2%) (UNII: R33S7TK2EP)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
EDETATE DISODIUM ANHYDROUS (UNII: 8NLQ36F6MM)	

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:51326-929-06	200 mL in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	03/15/2016	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph drug	M006	03/15/2016	

Labeler - Topiderm, Inc. (049121643)

Registrant - Topiderm, Inc. (049121643)

Establishment

Name	Address	ID/FEI	Business Operations
Topiderm, Inc.		049121643	MANUFACTURE(51326-929)

Establishment

Name	Address	ID/FEI	Business Operations
Topix Pharmaceuticals, Inc.		117745066	PACK(51326-929)