REPLENIX ACNE- benzoyl peroxide gel
Topiderm, Inc

Replenix® Acne Gel 5%

Drug Facts

Active ingredient

Benzoyl Peroxide, USP 5%

Purpose

Anti-acne

Uses

- Topical acne medication.

Warnings

- **When using this product avoid unnecessary sun exposure and use a sunscreen.**
- For external use only.
- Keep away from eyes, lips, and mouth.
- If irritation develops, discontinue use and consult a doctor.
- Using other topical acne medications at the same time or immediately following use of this product may increase dryness or irritation of the skin. If this occurs, consult a doctor.
- May bleach fabrics.
- **Keep out of reach of children.** If swallowed, seek professional assistance or contact a Poison Control Center immediately.

Directions

- Cleanse the skin thoroughly before applying.
- Apply a thin layer daily, then gradually increase to two or three times daily.
- If bothersome drying or peeling occurs, reduce applications.
- **If going outside, use a sunscreen.** If irritation or sensitivity develops, discontinue use of both products and consult a doctor.

Inactive ingredients

Carbomer, Purified Water, Sodium Hydroxymethylglycinate, Sodium Lauroyl Sarcosinate,

Stearic Acid.

PRINCIPAL DISPLAY PANEL - 57 g Tube Label

REPLENiX®
ACNE SOLUTIONS

Acne Gel
Benzoyl Peroxide USP, 5%
Net wt. 2 oz. (57 g)

Topix Pharmaceuticals, Inc.
N. Amityville, NY 11701

REPLENIX®
ACNE SOLUTIONS

Acne Gel

Benzoyl Peroxide USP, 5%

Net wt. 2 oz. (57 g)

Topix Pharmaceuticals, Inc.
N. Amityville, NY 11701

Drug Facts

Active ingredient **Purpose**

Benzoyl Peroxide, USP 5%.....Anti-acne

Uses ■ Topical acne medication.

Warnings

■ **When using this product avoid unnecessary sun exposure and use a sunscreen.** ■ For external use only. ■ Keep away from eyes, lips, and mouth. ■ If irritation develops, discontinue use and consult a doctor. ■ Using other topical acne medications at the same time or immediately following use of this product may increase dryness or irritation of the skin. If this occurs, consult a doctor. ■ May bleach fabrics. ■ **Keep out of reach of children.** If swallowed, seek professional assistance or contact a Poison Control Center immediately.

Directions

■ Cleanse the skin thoroughly before applying.
■ Apply a thin layer daily, then gradually increase to two or three times daily. ■ If bothersome drying or peeling occurs, reduce applications.
■ **If going outside, use a sunscreen.** If irritation or sensitivity develops, discontinue use of both products and consult a doctor.

Inactive ingredients Carbomer, Purified Water, Sodium Hydroxymethylglycinate, Sodium Lauroyl Sarcosinate, Stearic Acid. R0619 Made in U.S.A. 411

REPLENIX ACNE

benzoyl peroxide gel

Product Information

Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:51326-411
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
BENZOYL PEROXIDE (UNII: W9WZN9A0GM) (BENZOYL PEROXIDE - UNII:W9WZN9A0GM)	BENZOYL PEROXIDE	50 mg in 1 g

Inactive Ingredients

Ingredient Name	Strength
CARBOMER HOMOPOLYMER, UNSPECIFIED TYPE (UNII: 0A5MM307FC)	
WATER (UNII: 059QF0KO0R)	
SODIUM HYDROXYMETHYLGLYCINATE (UNII: DIG6BWZ9XT)	
SODIUM LAUROYL SARCOSINATE (UNII: 632GS99618)	
STEARIC ACID (UNII: 4ELV7Z65AP)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:51326-411-57	57 g in 1 TUBE; Type 0: Not a Combination Product	01/22/1993	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph drug	M006	01/22/1993	

Labeler - Topiderm, Inc (049121643)

Registrant - Topiderm, Inc. (049121643)

Establishment

Name	Address	ID/FEI	Business Operations
Topiderm, Inc		049121643	MANUFACTURE(51326-411)

Establishment

Name	Address	ID/FEI	Business Operations
Topix Pharmaceuticals, Inc.		117745066	PACK(51326-411)

Revised: 10/2019

Topiderm, Inc