REPLENIX ACNE- benzoyl peroxide gel
Topiderm, Inc.

Replenix® Acne Gel 10%

Drug Facts

Active ingredient

Benzoyl Peroxide, USP 10%

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, 10%

Net wt. 2 oz. (57 g)

Topix Pharmaceuticals, Inc.
N. Amityville, NY 11701

REPLENIX®
ACNE SOLUTIONS

Acne Gel

Benzoyl Peroxide USP, 10%

Net wt. 2 oz. (57 g)

Topix Pharmaceuticals, Inc.
N. Amityville, NY 11701

Drug Facts

Active ingredient	Purpose
Benzoyl Peroxide, USP 10%.....	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.

rev 09/18 Made in U.S.A. 412

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.

REPLENIX ACNE

benzoyl peroxide gel

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:51326-412
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
BENZOYL PEROXIDE (UNII: W9WZN9A0GM) (BENZOYL PEROXIDE - UNII:W9WZN9A0GM)	BENZOYL PEROXIDE	100 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:51326-412-57	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(51326-412)

Establishment

Name	Address	ID/FEI	Business Operations
Topix Pharmaceuticals, Inc.		117745066	PACK(51326-412)

Revised: 10/2019 Topiderm, Inc.