REPLENIX ACNE SOLUTION BENZOYL PEROXIDE WASH- benzoyl peroxide liquid
Topiderm, Inc.

Disclaimer: Most OTC drugs are not reviewed and approved by FDA, however they may be marketed if they comply with applicable regulations and policies. FDA has not evaluated whether this product complies.

REPLENIX® ACNE SOLUTIONS 5% BENZOYL PEROXIDE WASH

Drug Facts

Active ingredients

Benzoyl Peroxide USP, 5%

Purpose

Acne treatment

Uses

BP Wash is a therapeutic combination of sudsing cleanser and benzoyl peroxide for the treatment of acne.

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 or sensitivity 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, only one medication should be used unless directed by a doctor.
- May bleach fabrics.

- **Keep out of reach of children.** If swallowed, seek professional assistance or contact a Poison Control Center immediately.

Directions

- Shake well. Wet affected area, wash, and rinse well.
- Use once or twice daily or as directed by a physician.
- 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, Phenoxyethanol, Purified Water, Sodium Benzoate, Sodium C14-16 Olefin Sulfonate, Stearic Acid USP.

PRINCIPAL DISPLAY PANEL - 200 ml Tube Label

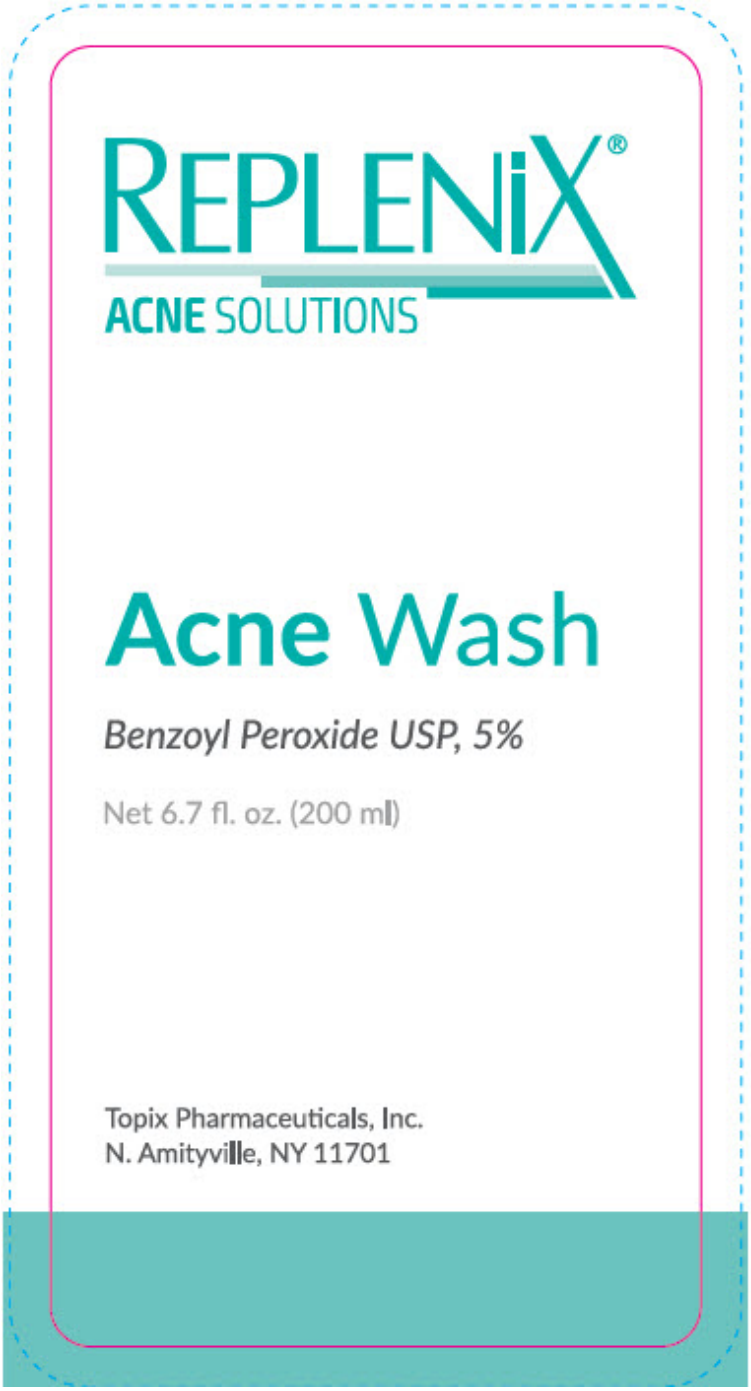
REPLENiX®
ACNE SOLUTIONS

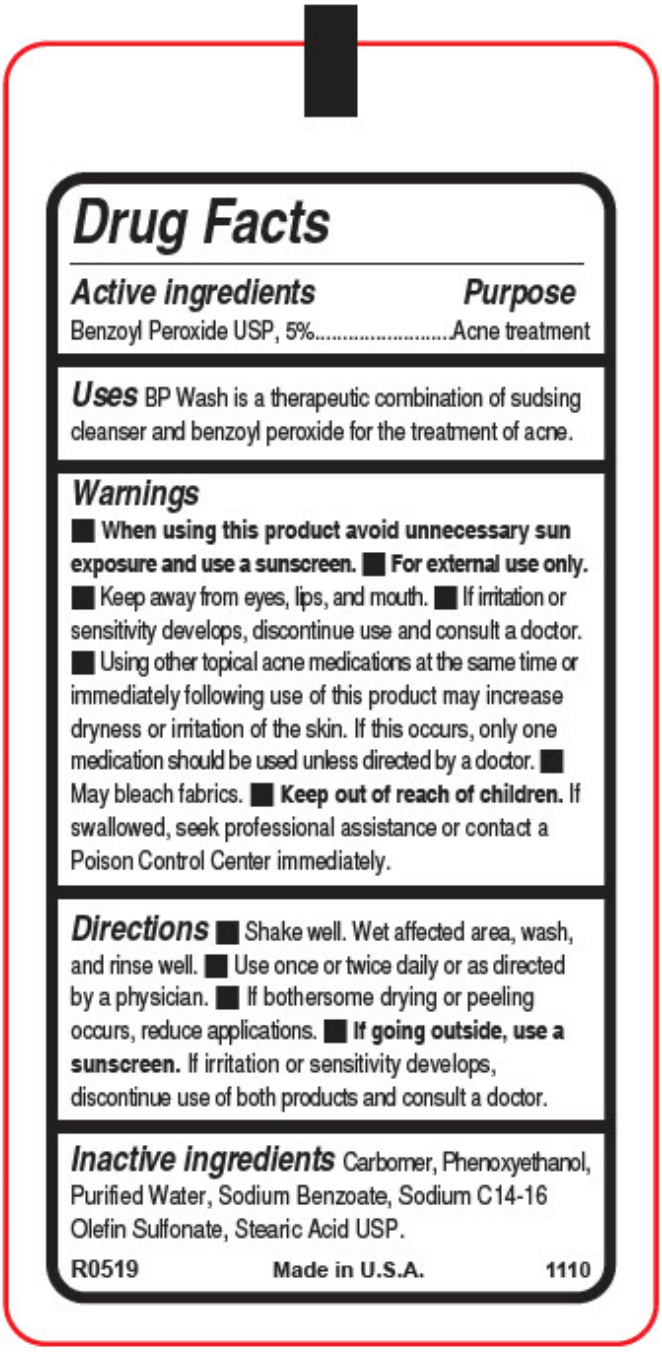
Acne Wash

Benzoyl Peroxide USP, 5%

Net 6.7 fl. oz. (200 ml)

Topix Pharmaceuticals, Inc.
N. Amityville, NY 11701





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Benzoyl Peroxide USP, 5% ..... Acne treatment

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R0519 **Made in U.S.A.** 1110

REPLENIX ACNE SOLUTION BENZOYL PEROXIDE WASH

benzoyl peroxide liquid

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:51326-111
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 mL

Inactive Ingredients

Ingredient Name	Strength
CARBOMER HOMOPOLYMER, UNSPECIFIED TYPE (UNII: 0A5MM307FC)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
WATER (UNII: 059QF0KO0R)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	
SODIUM C14-16 OLEFIN SULFONATE (UNII: O9W3D3YF5U)	
STEARIC ACID (UNII: 4ELV7Z65AP)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:51326-111-01	200 mL in 1 TUBE; Type 0: Not a Combination Product	11/01/2017	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH FINAL	part333D	11/01/2017	

Labeler - Topiderm, Inc. (049121643)

Establishment

Name	Address	ID/FEI	Business Operations
Topiderm, Inc.		049121643	MANUFACTURE(51326-111)

Revised: 12/2019 Topiderm, Inc.