

SKINCOACH TREAT- benzoyl peroxide gel
SKIN COACH SL.

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.

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 the 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



skincoach

TREAT

Benzoyl Peroxide USP, 5%
Acne Gel

Net wt 2 oz (57 g)

Drug Facts 

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Uses ■ Topical acne medication.

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Rev. 5/19 Made in USA NDC73047-003-01

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Carbomer, Purified Water, Sodium Hydroxymethylglycinate, Sodium Lauroyl Sarcosinate, Stearic Acid.

SKINCOACH TREAT

benzoyl peroxide gel

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:73047-003
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
BENZOYL PEROXIDE (UNII: W9WZN9A0GM) (BENZOYL PEROXIDE - UNII:W9WZN9A0GM)	BENZOYL PEROXIDE	5 g in 100 g

Inactive Ingredients

Ingredient Name	Strength
CARBOXYPOLYMETHYLENE (UNII: 0A5MM307FC)	
WATER (UNII: 059QF0K00R)	
SODIUM HYDROXYMETHYLGLYCINATE (UNII: DIG6BWZ9XT)	
SODIUM LAUROYL SARCO SINATE (UNII: 632GS99618)	
STEARIC ACID (UNII: 4ELV7Z65AP)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:73047-003-01	57 g in 1 TUBE; Type 0: Not a Combination Product	05/21/2019	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date

OTC monograph final	part333D	05/21/2019	
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Labeler - SKIN COACH SL. (468534978)

Registrant - SKIN COACH SL. (468534978)

Establishment

Name	Address	ID/FEI	Business Operations
Topiderm Inc. II		078841698	manufacture(73047-003)

Revised: 5/2019

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