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 2.5%----- 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 childen. If swallowed, seek professional assistance or contact a Poison Control Center immediately.

Directions

■ Cleanse the skin thoroughly belore 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 initation or sensitivity develops, discontinue use of both products and consult a doctor.

Inactive ingredients

Carbomer, Purified Water, Sodium hydroxymethylglycinate, Sodium Laurovl sarcosinate, Stearic Acid.

Principal display panel





Benzoyl Peroxide USP, 2.5% Acne Gel

Net wt 2 oz (57 g)



Directions

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 If irritation or sensitivitydevelops,
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SKINCOACH TREAT

benzoyl peroxide gel

Product Type HUMAN OTC DRUG Item Code (Source) NDC:73047-002

Route of Administration TOPICAL

Active Ingredient/Active Moiety

Ingredient Name Basis of Strength Strength

BENZOYL PEROXIDE (UNII: W9 WZN9 A0 GM) (BENZOYL PEROXIDE - UNII: W9 WZN9 A0 GM) | BENZOYL PEROXIDE | 2.5 g in 100 g

Inactive Ingredients	
Ingredient Name	Strength
CARBO XYPO LYMETHYLENE (UNII: 0 A5MM307FC)	
WATER (UNII: 059QF0KO0R)	
SO DIUM HYDRO XYMETHYLGLYCINATE (UNII: DIG6 BWZ9 XT)	
SODIUM LAURO YL SARCO SINATE (UNII: 632GS99618)	
STEARIC ACID (UNII: 4ELV7Z65AP)	

ı	Packaging				
l	# Item Code	Package Description	Marketing Start Date	Marketing End Date	
ı	1 NDC:73047-002-01	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	

Labeler - SKIN COACH SL. (468534978)

Registrant - SKIN COACH SL. (468534978)

Establishment				
Name	Address	ID/FEI	Business Operations	
Topiderm Inc. II		078841698	manufacture(73047-002)	

Revised: 5/2019 SKIN COACHSL.