

THERASPEC ACNE CLEANSER- benzoyl peroxide soap

Salient Labs, LLC

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.

TheraSpec Acne Cleanser

**TheraSpec
therapeutic specific cleansers
Acne Cleanser
Micronized BPO**

Drug Facts Panel

Active Ingredient

Benzoyl Peroxide 5%

Acne medication

Use

for the treatment of acne

Warnings

For external use only

Do not use this medication if you have very sensitive skin or if you are sensitive to benzoyl peroxide

When using this product

- keep away from eyes, lips and mouth
- avoid unnecessary sun exposure and use a sunscreen
- avoid contact with hair, dyed fabric, including carpet and clothing which may be bleached by this product
- skin irritation may occur, characterized by redness, burning, itching, peeling, or possibly swelling. Mild irritation may be reduced by using the product less frequently or in a lower concentration. If irritation becomes severe, discontinue use: if irritation still continues, consult a doctor.
- using other topical acne medications at the same time or immediately following the 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.

Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away. Avoid contact with eyes. If contact occurs, flush thoroughly with water.

Directions Wet face. Gently massage all over face for 20-30 seconds, avoiding eye area. Rinse thoroughly and pat dry. Recommended for use twice daily.

Inactive Ingredients Acrylates Copolymer, Allantoin, Aqua (Deionized Water), Benzyl Alcohol, Cetareth-20, Dehydroacetic Acid, Hydrolyzed Jojoba Esters, Isopentyl diol, Jojoba Esters, Sodium Cocyl Isethionate.

TheraSpec

Acne Cleanser
 Principal Display Panel
 221 ml
 NDC: 52205-003-00



Acne Cleanser
 Micronized BPO



7.5 fl. oz. / 221 ml

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Warnings For external use only Do not use this medication if you have sensitive skin or if you are sensitive to benzoyl peroxide
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TheraSpec™ is a line of thoughtfully formulated cleansers design to address specific skin conditions.

TheraSpec™ Acne Cleanser uses micronized benzoyl peroxide (BPO) which makes the active ingredient less irritating. This cleanser also leverages a holistic moisturizing complex that leaves the skin feeling smooth and soft. The pH of this product has been balanced to ensure a gentle, thorough cleansing without the harshness associated with traditional acne products.

ADV SKIN TECH
 Manufactured for Salient Labs
 d/b/a Advanced Skin Technology
 Fletcher, NC - Made in the USA
 Toll Free 866-642-7546
 www.advskintech.com



THERASPEC ACNE CLEANSER

benzoyl peroxide soap

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:52205-003
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 mL

Inactive Ingredients

Ingredient Name	Strength
BUTYL ACRYLATE/METHYL METHACRYLATE/METHACRYLIC ACID COPOLYMER (18000 MW) (UNII: JZ1374NL9E)	
HYDROLYZED JOJOBA ESTERS (ACID FORM) (UNII: UDR641JW8W)	
ALLANTOIN (UNII: 344S277G0Z)	
WATER (UNII: 059QF0KO0R)	
SODIUM COCOYL ISETHIONATE (UNII: 518XTE8493)	
DEHYDROACETIC ACID (UNII: 2KAG279R6R)	
ISOPENTYLDIOL (UNII: 19NOL5474Q)	
JOJOBA OIL, RANDOMIZED (UNII: 7F0EV20QYL)	
BENZYL ALCOHOL (UNII: LKG8494WBH)	
POLYOXYL 20 CETOSTEARYL ETHER (UNII: YRC528SWUY)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:52205-003-00	221 mL in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	04/18/2019	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part333D	04/18/2019	

Labeler - Salient Labs, LLC (130977940)

Establishment

Name	Address	ID/FEI	Business Operations
Pure Source, LLC		080354456	manufacture(52205-003)

Revised: 11/2019

Salient Labs, LLC