

BPT10.1 ACNE TREATMENT- benzoyl peroxide lotion
Create Cosmetics, LLC

CREATE COSMETICS - BPT10.1 ACNE TREATMENT (70162-103)

ACTIVE INGREDIENT

BENZOYL PEROXIDE 10%

PURPOSE

ACNE TREATMENT

USE

FOR THE TREATMENT OF ACNE.

WARNINGS

FOR EXTERNAL USE ONLY

DO NOT USE IF YOU:

- HAVE VERY SENSITIVE SKIN.
- ARE SENSITIVE TO BENZOYL PEROXIDE.

WHEN USING THIS PRODUCT

- SKIN IRRITATION AND DRYNESS IS MORE LIKELY TO OCCUR IF YOU USE ANOTHER TOPICAL ACNE MEDICATION AT THE SAME TIME. IF IRRITATION OCCURS, ONLY USE ONE TOPICAL ACNE MEDICATION AT A TIME.
- AVOID UNNECESSARY SUN EXPOSURE AND USE A SUNSCREEN.
- AVOID CONTACT WITH THE EYES, LIPS, AND MOUTH.
- AVOID CONTACT WITH HAIR AND DYED FABRICS, WHICH MAY BE BLEACHED BY THIS PRODUCT.
- SKIN IRRITATION MAY OCCUR, CHARACTERIZED BY REDNESS, BURNING, ITCHING, PEELING, OR POSSIBLY SWELLING. IRRITATION MAY BE REDUCED BY USING THE PRODUCT LESS FREQUENTLY OR IN A LOWER CONCENTRATION.

STOP USE AND ASK A DOCTOR IF

- IRRITATION BECOMES SEVERE.

KEEP OUT OF REACH OF CHILDREN. IF SWALLOWED, GET MEDICAL HELP OR CONTACT A POISON CONTROL CENTER RIGHT AWAY.

DIRECTIONS

SENSITIVITY TEST FOR A NEW USER.

- APPLY PRODUCT SPARINGLY TO ONE OR TWO SMALL AFFECTED AREAS DURING THE

FIRST 3 DAYS. IF NO DISCOMFORT OCCURS, FOLLOW THE DIRECTIONS STATED BELOW.

- CLEAN THE SKIN THOROUGHLY BEFORE APPLYING THIS PRODUCT.
- COVER THE ENTIRE AFFECTED AREA WITH A THIN LAYER ONE TO THREE TIMES DAILY.
- BECAUSE EXCESSIVE DRYING OF THE SKIN MAY OCCUR, START WITH ONE APPLICATION DAILY, THEN GRADUALLY INCREASE TO TWO OR THREE TIMES DAILY IF NEEDED OR AS DIRECTED BY A DOCTOR.
- IF BOTHERSOME DRYNESS OR PEELING OCCURS, REDUCE APPLICATION TO ONCE A DAY OR EVERY OTHER DAY.
- IF GOING OUTSIDE, APPLY SUNSCREEN AFTER USING THIS PRODUCT. IF IRRITATION OR SENSITIVITY DEVELOPS, STOP USE OF BOTH PRODUCTS AND ASK A DOCTOR.

OTHER INFORMATION

- ORGANIC INGREDIENTS ARE DENOTED WITH THE *.

INACTIVE INGREDIENTS

WATER, SIMMONDSIA CHINENSIS (JOJOBA) SEED OIL*, EMULSIFYING WAX NF, HAMAMELIS VIRGINIANA (WITCH HAZEL) WATER, MACADAMIA TERNIFOLIA (MACADAMIA NUT) SEED OIL*, SODIUM PCA, STEARIC ACID, BUTYROSPERMUM PARKII (SHEA) BUTTER*, GLYCERIN, PHENOXYETHANOL, CAPRYLYL GLYCOL, SORBIC ACID, MELALEUCA ALTERNIFOLIA (TEA TREE) LEAF OIL*, ALLANTOIN, SCLEROTIUM GUM.

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Drug Facts

Active Ingredient	Purpose
Benzoyl Peroxide 10%	Acne Treatment

Use For the treatment of acne

Warnings For external use only.

Do not use if you:

- have very sensitive skin.
- are sensitive to benzoyl peroxide.

When using this product

- skin irritation and dryness are more likely to occur if you use another topical acne medication at the same time. If irritation occurs, only use one topical acne medication at a time.
- avoid unnecessary sun exposure and use a sunscreen.
- avoid contact with the eyes, lips, and mouth.
- avoid contact with hair and dyed fabrics, which may be bleached by this product.
- skin irritation may occur, characterized by redness, burning, itching, peeling, or possibly swelling. Irritation may be reduced by using the product less frequently or in a lower concentration.

Stop use and ask a doctor if

- irritation becomes severe.

Keep out of reach of children.

If swallowed, get medical help or contact a Poison Control Center right away.

Directions

Sensitivity Test for a New User.

- Apply product sparingly to one or two small affected areas during the first 3 days. If no discomfort occurs, follow the directions stated below.
- clean the skin thoroughly before applying this product.
- cover the entire affected area with a thin layer one to three times daily.
- because excessive drying of the skin may occur, start with one application daily, then gradually increase to two or three times daily if needed or as directed by a doctor.
- if bothersome dryness or peeling occurs, reduce application to once a day or every other day.
- if going outside, apply sunscreen after using this product. If irritation or sensitivity develops, stop use of both products and ask a doctor.

Other information

- Organic ingredients are denoted by *

Inactive ingredients

Water, Simmondsia Chinensis (Jojoba) Seed Oil*, Emulsifying Wax NF, Hamamelis Virginiana (Witch Hazel) Water, Macadamia Ternstroemia (Macadamia Nut) Seed Oil*, Sodium PCA, Stearic acid, Butyrospermum Parkii (Shea) Butter*, Glycerin, Phenoxethanol, Caprylyl Glycol, Sorbic Acid, Melaleuca Alternifolia (Tea Tree) Leaf Oil*, Allantoin, Sclerosium Gum.

ABOUT THE COMPANY

Create Cosmetics was founded in 2012 by three scientists in San Francisco: Johan Aardal BSc, Nick Conley PhD and Fiona Plows PhD. All of us had an interest in skincare, and I, a life-long acne problem.

We discovered that natural plant-based oils can work as effective carriers for man-made synthetics, so we took a potent moisturizing base formula, added Benzoyl Peroxide, and created an acne treatment that both combats acne and nurtures the skin.

Johan Aardal

Johan Aardal
Founder

CONTACT INFORMATION

We'd love to hear from you!

+1 888-558-6295

hi@createcosmetics.com

createcosmetics.com

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San Francisco, CA 94117

CREATE
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ABOUT THE FORMULA

Our 10% Benzoyl Peroxide and Tea Tree Oil formula was designed for those who tolerate Benzoyl Peroxide well and have acne or backne not cleared by our 3% formula. It combines nurturing natural ingredients with effective man-made synthetics. The lightweight oil-in-water design absorbs quickly into the skin, leaving no residue, while its natural non-comedogenic oils aid skin penetration of Benzoyl Peroxide and helps prevent excessive drying. We included tea tree oil for its bacteriostatic effects.

For better effect we recommend using our Glycolic Acid 5 ELEMENTS CLEANSER daily.

INGREDIENT INFORMATION

89% NATURAL RAW MATERIALS

55% ORGANIC RAW MATERIALS

14% PLANT BASED OILS

Non-pore-blocking oils that nurture the skin and aid penetration.

11% MAN-MADE RAW MATERIALS

With the lowest possible hazard rating.

0% ANIMAL TESTING, INGREDIENTS, DYES OR FRAGRANCE

BPT 10.1

ACNE TREATMENT
CYSTIC AND SEVERE ACNE

10% BENZOYL PEROXIDE
1% ORGANIC TEA TREE OIL

2.2 fl.oz • 64 ml e



ASIN:B0109QIFD8

V1

BPT10.1 ACNE TREATMENT

benzoyl peroxide lotion

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:70162-103
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
BENZOYL PEROXIDE (UNII: W9WZN9A0GM) (BENZOYL PEROXIDE - UNII:W9WZN9A0GM)	BENZOYL PEROXIDE	10 g in 100 mL

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
JOJOBA OIL (UNII: 724GKU717M)	
CETOSTEARYL ALCOHOL (UNII: 2DMT128M1S)	
POLYSORBATE 60 (UNII: CAL22UVI4M)	
WITCH HAZEL (UNII: 101I4J0U34)	
MACADAMIA OIL (UNII: 515610SU8C)	
SODIUM PYRROLIDONE CARBOXYLATE (UNII: 469OTG57A2)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
SHEA BUTTER (UNII: K49155WL9Y)	
GLYCERIN (UNII: PDC6A3C0OX)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
CAPRYLYL GLYCOL (UNII: 00YIU5438U)	
SORBIC ACID (UNII: X045WJ989B)	
TEA TREE OIL (UNII: VIF565UC2G)	
ALLANTOIN (UNII: 344S277G0Z)	
BETASIZOFIRAN (UNII: 2X51AD1X3T)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:70162-103-51	1 in 1 BOX	07/27/2020	
1	NDC:70162-103-11	64 mL in 1 TUBE; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
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OTC Monograph Drug M006

07/27/2020

Labeler - Create Cosmetics, LLC (057569916)

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Create Cosmetics, LLC