

ZO SKIN HEALTH ACNE CONTROL BENZOYL PEROXIDE- benzoyl peroxide cream
ZO Skin Health, 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.

ZO[®] Skin Health Acne Control 10% Benzoyl Peroxide

National Drug Code 42851-087-60

Drug Facts

Active Ingredient

Benzoyl Peroxide 10%

Purpose

Acne Medication

Uses

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

- Protect this product from excessive heat and direct sun.

Inactive Ingredients

Aqua/Water/Eau, Aspalathus Linearis Leaf Extract, Camellia Sinensis Leaf Extract, Carbomer, Diethylhexyl Sodium Sulfosuccinate, Dimethicone, Disodium EDTA, Ethylhexylglycerin, Glycerin, Melaleuca Alternifolia (Tea Tree) Leaf Oil, PEG-40 Stearate, PEG-8 Laurate, Phenoxyethanol, Pinus Strobus Bark Extract, Polyglyceryl-6 Isostearate, Propanediol, Propylene Glycol, Silica, Sodium Citrate, Sodium Hydroxide, Sorbitan Stearate, Vitis Vinifera (Grape) Seed Extract, Xanthan Gum.

Dist. by ZO Skin Health, Inc. Irvine, CA 92618

PRINCIPAL DISPLAY PANEL - 60 mL Tube Carton

ZO[®] SKIN HEALTH

BY ZEIN OBAGI MD

NDC 42851-087-60

ACNE CONTROL

10% Benzoyl Peroxide

60 mL / 2 Fl. Oz.



ACNE

ZO SKIN HEALTH

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ACNE CONTROL

10% Benzoyl Peroxide

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Drug Facts (Continued)

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Maximum-strength acne-fighting formula that controls surface oil, neutralizes bacteria, and prevents future breakouts.

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Dist. by ZO Skin Health, Inc. Irvine, CA 92618
Made in USA with US & Imported materials
zoeskinhealth.com | 907000



ZO SKIN HEALTH ACNE CONTROL BENZOYL PEROXIDE

benzoyl peroxide cream

Product Information

| | | | |
|--------------------------------|----------------|---------------------------|---------------|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:42851-087 |
| Route of Administration | TOPICAL | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|---|--------------------------|-------------------|
| BENZOYL PEROXIDE (UNII: W9WZN9A0GM) (BENZOYL PEROXIDE - UNII:W9WZN9A0GM) | BENZOYL PEROXIDE | 100 mg in 1 mL |

Inactive Ingredients

| Ingredient Name | Strength |
|--|-----------------|
| WATER (UNII: 059QF0KO0R) | |
| ASPALATHUS LINEARIS LEAF (UNII: H7UGK1GJCU) | |
| GREEN TEA LEAF (UNII: W2ZU1RY8B0) | |
| CARBOMER HOMOPOLYMER, UNSPECIFIED TYPE (UNII: 0A5MM307FC) | |
| DOCUSATE SODIUM (UNII: F05Q2T2JA0) | |
| DIMETHICONE (UNII: 92RU3N3Y10) | |
| EDETATE DISODIUM ANHYDROUS (UNII: 8NLQ36F6MM) | |
| ETHYLHEXYLGLYCERIN (UNII: 147D247K3P) | |
| GLYCERIN (UNII: PDC6A3C0OX) | |
| TEA TREE OIL (UNII: VIF565UC2G) | |
| PEG-40 STEARATE (UNII: ECU18C66Q7) | |
| PEG-8 LAURATE (UNII: 762O8IWA10) | |
| PHENOXYETHANOL (UNII: HIE492ZZ3T) | |
| PINUS STROBUS BARK (UNII: 8PJ4761097) | |
| POLYGLYCERYL-6 ISOSTEARATE (UNII: 5VKGO1003G) | |
| PROPANEDIOL (UNII: 5965N8W85T) | |
| PROPYLENE GLYCOL (UNII: 6DC9Q167V3) | |
| SILICON DIOXIDE (UNII: ETJ7Z6XBU4) | |
| SODIUM CITRATE, UNSPECIFIED FORM (UNII: 1Q73Q2JULR) | |
| SODIUM HYDROXIDE (UNII: 55X04QC32I) | |
| SORBITAN MONOSTEARATE (UNII: NVZ4I0H58X) | |
| VITIS VINIFERA SEED (UNII: C34U15ICXA) | |
| XANTHAN GUM (UNII: TTV12P4NEE) | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|--|----------------------|--------------------|
| 1 | NDC:42851-087-60 | 1 in 1 CARTON | 05/25/2023 | |
| 1 | | 60 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 |
|---------------------|--|----------------------|--------------------|
| OTC monograph final | part333D | 05/25/2023 | |

Labeler - ZO Skin Health, Inc. (826468527)

Revised: 5/2023

ZO Skin Health, Inc.