

CLEARASIL STUBBORN ACNE CONTROL 5IN1 SPOT TREATMENT- benzoyl peroxide cream
RB Health (US) 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.

Clearasil® Stubborn Acne Control 5in1 Spot Treatment Cream

Drug Facts

Active ingredient

Benzoyl peroxide 10%

Purpose

Acne medication

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

- **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 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.
- 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

- 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

- **keep outer box for full product information**
- keep tightly closed
- store at 20-25 °C (68-77 °F)

Inactive ingredients

Water, Propylene Glycol, Aluminum Hydroxide, Bentonite, Glyceryl Stearate SE, PEG-12, Isopropyl Myristate, Methylparaben, Carbomer, Potassium Hydroxide, Propylparaben

Questions?

1-866-25-CLEAR (1-866-252-5327). You may also report side effects to this phone number.

Distributed By:
RB Health (US),
Parsippany, NJ 07054-0224

PRINCIPAL DISPLAY PANEL - 28 g Tube Carton

Clearasil®

**STUBBORN ACNE CONTROL
5IN1 SPOT TREATMENT CREAM**

Benzoyl Peroxide Acne Medication

FIGHTS

5

**STUBBORN
ACNE
PROBLEMS**

MAXIMUM STRENGTH

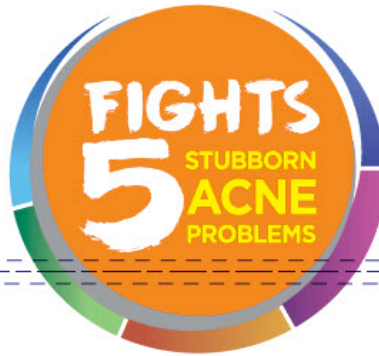
***FIGHTS 1. BLOCKED PORES 2. PIMPLE SIZE
3. EXCESS OIL 4. ACNE MARKS 5. BLACKHEADS***

Net wt. 1 oz (28 g)

Clearasil

STUBBORN ACNE CONTROL 5 IN 1 SPOT TREATMENT CREAM

Benzoyl Peroxide Acne Medication



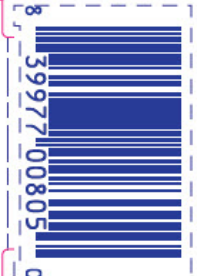
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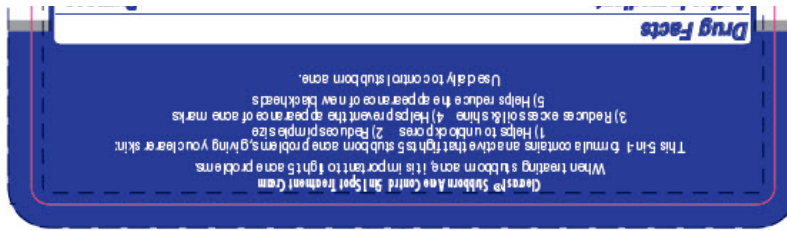
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Net wt. 1 oz (28 g)

Active ingredient Benzoyl peroxide 10%
Purpose Acne medication
Use for the treatment of acne
Warnings For external use only
Do not use if you have very sensitive skin or are sensitive to benzoyl peroxide
When using this product, avoid unnecessary sun exposure and use a sunscreen
Do not contact with the eyes, lips and mouth
Do not contact with hair and dyed fabrics, which may be bleached by this product
Do not use in conjunction with other acne medications at the same time. If skin irritation and dryness is more likely to occur if you use another topical acne medication at the same time, it may be reduced by using the product less frequently or in a lower concentration.
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 Cleanse skin thoroughly before applying this product
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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 Keep out of reach for children for full product information ■ keep tightly closed ■ store at 20-25 °C (68-77 °F)
PEG-12, lauryl myristate, methylparaben, carbomer, potassium hydroxide, benzalkonium chloride, glyceryl stearate SE
Inactive ingredients water, propylene glycol, aluminum hydroxide, benzalkonium chloride, glyceryl stearate SE
1-800-25-CLEAR (1-800-252-6227). You may also report side effects to the phone number
Distributed By:
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patients: www.tb.com/patients
www.dergasil.us
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CLEARASIL STUBBORN ACNE CONTROL 5IN1 SPOT TREATMENT

benzoyl peroxide cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:63824-438
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 g

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
ALUMINUM HYDROXIDE (UNII: 5QB0T2IU00)	
BENTONITE (UNII: A3N5ZCN45C)	
GLYCERYL STEARATE SE (UNII: FCZ5MH785I)	
POLYETHYLENE GLYCOL 600 (UNII: NL4J9F21N9)	
ISOPROPYL MYRISTATE (UNII: 0RE8K4LNJS)	
METHYLPARABEN (UNII: A2I8C7HI9T)	
CARBOMER HOMOPOLYMER, UNSPECIFIED TYPE (UNII: 0A5MM307FC)	
POTASSIUM HYDROXIDE (UNII: WZH3C48M4T)	
PROPYLPARABEN (UNII: Z8IX2SC1OH)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:63824-438-01	1 in 1 CARTON	12/06/2017	
1		28 g 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	12/06/2017	

Labeler - RB Health (US) LLC (081049410)

Revised: 1/2022

RB Health (US) LLC