

NEUTROGENA ON-THE-SPOT ACNE TREATMENT VANISHING FORMULA- benzoyl peroxide cream

Johnson & Johnson Consumer 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.

Neutrogena® On-the-Spot® Acne Treatment

Drug Facts

Active Ingredients

Benzoyl Peroxide (2.5%)

Purpose

Acne Medication

Use

For the treatment of acne.

Warnings

For external use only.

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.

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 or 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

- 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

- Store at 20°C to 25°C (68°F - 77° F)

Inactive Ingredients

Water, Carbomer Homopolymer type B, Ethylhexylglycerin, Sodium Hydroxide, Chlorphenesin, Disodium EDTA, Laureth-4, Hydroxypropyl Methylcellulose

Questions?

Call toll-free 800-582-4048 or 215-273-8755 (collect). www.neutrogena.com

Distributed by: **JOHNSON & JOHNSON
CONSUMER INC.**
Skillman, NJ 08558

PRINCIPAL DISPLAY PANEL - 21g Tube Carton

VANISHING CREAM FORMULA

On-the-Spot®

Acne Treatment

**fights acne-causing bacteria
 while gentle on skin**

**benzoyl peroxide acne medication
 CLINICALLY PROVEN POWER**

**Tough on Acne,
 Easy on Your Skin**

Neutrogena®

DERMATOLOGIST RECOMMENDED

NET WT .75 OZ (21g)

VANISHING CREAM FORMULA

On-the-Spot[®]

Acne Treatment

fights acne-causing bacteria
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benzoyl peroxide acne medication

CLINICALLY PROVEN POWER

**Tough on Acne,
Easy on Your Skin**

Neutrogena[®]

DERMATOLOGIST RECOMMENDED

NET WT 0.75 OZ (21 g)

VANISHING CREAM FORMULA ABSORBS QUICKLY, WORKS INVISIBLY

Some medicated spot treatments contain 10% benzoyl peroxide that can irritate skin, causing redness and dryness which can make acne worse. Neutrogena® On-the-Spot® Acne Treatment is clinically proven to be strong and effective in fighting acne while gentle on skin.

CLINICALLY PROVEN EFFECTIVENESS

WITH NO BURNING; WON'T DRY OUT SKIN

Neutrogena® On-the-Spot® Acne Treatment contains just 2.5% benzoyl peroxide, yet is clinically proven to be so effective that skin starts getting clearer on day 1 — all without over-drying, stinging or burning skin. This fast working formula is so lightweight that it quickly absorbs into skin. It goes deep down in the pores to kill the acne bacteria that cause pimples and helps to prevent new ones from forming.

WORKS HARD HOUR AFTER HOUR

TO KEEP SKIN HEALTHY-LOOKING

Helps relieve redness of acne pimples without over-drying skin. **Long-lasting protection.**

Works hour after hour to treat acne all day long.

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CONSUMER INC.

Skillman, NJ 08558 © J&JCI 2016

Active Made in Mexico 30032720



Drug Facts

Active ingredient Benzoyl Peroxide 2.5% Acne Medication

Use For the treatment of acne.

Warnings For external use only

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.

Do not use if you ■ have very sensitive skin, ■ are sensitive to benzoyl peroxide.

When using this product ■ avoid unnecessary sun exposure and use 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, 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.

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benzoyl peroxide cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:69968-0164
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
BENZOYL PEROXIDE (UNII: W9WZN9A0GM) (BENZOYL PEROXIDE - UNII:W9WZN9A0GM)	BENZOYL PEROXIDE	25 mg in 1 g

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
CARBOMER HOMOPOLYMER TYPE B (ALLYL PENTAERYTHRITOL OR ALLYL SUCROSE CROSSLINKED) (UNII: K6MOM3T5YL)	
ETHYLHEXYLGLYCERIN (UNII: 147D247K3P)	
SODIUM HYDROXIDE (UNII: 55X04QC32I)	
CHLORPHENESIN (UNII: I670DAL4SZ)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	
LAURETH-4 (UNII: 6HQ855798J)	
HYPROMELLOSE, UNSPECIFIED (UNII: 3NXW29V3WO)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:69968-0164-1	1 in 1 CARTON	02/01/2016	
1		21 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	02/01/2016	

Labeler - Johnson & Johnson Consumer Inc. (118772437)