ZITFREE ACNE TREATMENT- benzoyl peroxide ointment
Natureplex 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.

ZITFREE
ACNE TREATMENT

Drug Facts

Active ingredient

Benzoyl peroxide 10%

Purpose

Acne treatment

Uses

- treats acne
- dries acne pimples and allows skin to heal
- helps prevent new acne pimples from forming

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 consult a doctor if irritation becomes severe.

If pregnant or breast-feeding, ask a health professional before use.

Keep out of reach of children. In case of accidental ingestion, get medical help or contact a Poison Control Center right away: 800-222-1222.

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 up to 3 times daily

- because excessive drying of the skin may occur, start with 1 application daily, then gradually increase to 2 to 3 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, use sunscreen after using this product. If irritation or sensitivity develops, stop use of both products and ask a doctor.

Other information

- store at 15 to 30°C (59 to 86°F)
- **Tamper Evident:** DO NOT USE IF SEAL ON TUBE IS BROKEN OR MISSING.

Inactive ingredients

carbomer, disodium EDTA, hydroxypropyl methylcellulose, laureth-4, methylparaben, purified water, sodium hydroxide

Questions or comments?

866-323-0107 or visit www.natureplex.com

PRINCIPAL DISPLAY PANEL - 28 g Tube Carton

NDC 67234-035-01

Natureplex™

MAXIMUM STRENGTH

Zit*Free*
Acne Treatment Cream

**** Compare to the***
active ingredient of
Clearasil ® Daily
Clear ® Vanishing
Acne Treatment Cream

Oil-Free, Odorless Cream Disappears As It Works

NET WT 1 OZ (28g)

Natureplex

MAXIMUM STRENGTH

ZitFree

Acne Treatment Cream

10% BENZOYL PEROXIDE

QUALITY NATUREPLEX GUARANTEE

Dries and clears existing blemishes & helps prevent new ones from forming

3086B
V03

NDC 67234-035-01

Natureplex

MAXIMUM STRENGTH

ZitFree

Acne Treatment Cream

*Compare to the active ingredient of Clearasil® Daily Clear® Vanishing Acne Treatment Cream

Oil-Free, Odorless Cream Disappears As It Works

NET WT 1 OZ (28g)

ZitFree

Acne Treatment Cream

Natureplex

MAXIMUM STRENGTH

ZitFree

Acne Treatment Cream

*This product is not manufactured by or distributed by Reckitt Benckiser Group plc, the distributor of Clearasil® Daily Clear® Vanishing Acne Treatment Cream.

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Natureplex

MADE IN THE USA

NATUREPLEX, Olive Branch, MS 38654

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Active Ingredient	Purpose
Benzoyl peroxide 10%.....	Acne treatment

Uses ▪ treats acne ▪ dries acne pimples and allows skin to heal ▪ helps prevent new acne pimples from forming

Warnings

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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 sunscreen ▪ avoid contact with 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 consult a doctor if irritation becomes severe.

If pregnant or breast-feeding ask a health professional before use.

Keep out of reach of children. In case of accidental

Drug Facts (continued)

ingestion, get medical help or contact a Poison Control Center right away: 800 222 1222

Directions

▪ Sensitivity Test for a New User: Apply product sparingly to one entire small affected area 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 up to 3 times daily ▪ because excessive drying of the skin may occur, start with 1 application daily, then gradually increase to 2 to 3 times daily if needed or as directed by a doctor. ▪ If tolerance/dryness or peeling occurs, reduce application to once a day or every other day ▪ If going outside, use sunscreen after using this product. If irritation or sensitivity develops, stop use of both products and ask a doctor.

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ZITFREE ACNE TREATMENT

benzoyl peroxide ointment

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:67234-035
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 g

Inactive Ingredients	
Ingredient Name	**Strength**
CARBOMER HOMOPOLYMER TYPE C (ALLYL PENTAERYTHRITOL CROSSLINKED) (UNII: 4Q93RCW27E)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	
HYPROMELLOSE, UNSPECIFIED (UNII: 3NXW29V3WO)	
LAURETH-4 (UNII: 6HQ855798J)	
METHYLPARABEN (UNII: A2I8C7HI9T)	
WATER (UNII: 059QF0KO0R)	
SODIUM HYDROXIDE (UNII: 55X04QC32I)	

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:67234-035-01	1 in 1 CARTON	12/01/2014	
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	12/01/2014	

Labeler - Natureplex LLC (062808196)

Establishment

Name	Address	ID/FEI	Business Operations
Natureplex LLC		062808196	MANUFACTURE(67234-035)