

LEADER MAXIMUM STRENGTH INVISIBLE ACNE - benzoyl peroxide 10% cream
Cardinal Health

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.

Drug Facts

☐Active ingredient

Benzoyl Peroxide 10%

☐Purpose

Acne treatment cream

☐Uses

- treats acne
- dries up acne pimples
- helps prevent new acne pimples

☐Warnings

☐For external use only

☐Do not use

- on broken skin
- on large areas of the body
- if you have sensitive skin or are sensitive to benzoyl peroxide

☐When using this product

- apply to affected areas only
- avoid unnecessary sun exposure and use a sunscreen
- do not use in or near eyes
- this product may bleach hair or dyed fabrics
- with other topical acne medications at the same time or immediately following use of this product may increase dryness or irritation of the skin. Only one medication should be used unless directed by a physician
- skin irritation may occur characterized by redness, burning, itching, peeling or possible swelling

☐Stop and ask a doctor if

- too much irritation or sensitivity develops or increases

☐Keep out of reach of children

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

Directions

- cleanse the skin thoroughly before applying
- cover the entire affected area with a thin layer 1 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 a sunscreen. Allow benzoyl peroxide to dry, then follow directions in the sunscreen labeling.

☐ ***Other information***

- keep tightly closed
- keep away from heat

☐ ***Inactive ingredients***

Aluminum hydroxide gel, Carbomer 940, Glyceryl monostearate, Isopropyl myristate, Magnesium aluminum silicate, Methylparaben, PEG 12, Propylene glycol, Propylparaben, Purified water

Leader Invisible Acne Cream

☐ **Maximum Strength**

☐ 10% Benzoyl Peroxide

tube image

107.95mm

LEADER *Maximum Strength*
Invisible Acne Cream Net Wt. 1oz. (28g)

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 Dublin, Ohio 43017 CIN# 331052 www.myleader.com 1304630 Rev. 6/08



Leader Invisible Acne Cream
 Maximum Strength
 10% Benzoyl Peroxide
 carton image

1.205x3.2x3.2cm

LEADER *Maximum Strength*
Invisible Acne Cream
Helps prevent future pimples from forming.

Acne Medication with 10% Benzoyl Peroxide

NDC: 37205-279-10
 *Compare to the active ingredient in Clearasil Vanishing Cream



LEADER® Maximum Strength **SATISFACTION GUARANTEED**

Invisible Acne Cream

Acne Medication with 10% Benzoyl Peroxide **Net Wt. 1oz. (28g)**

DISTRIBUTED BY:
CARDINAL HEALTH
 Dublin, Ohio 43017
 CIN 3310521
 1-800-200-6313
 www.myleader.com

All Leader® Brand products are 100% satisfaction guaranteed or return to place of purchase for a full refund.

Cat. No. F0463-000



*This product is not manufactured or distributed by Boots Healthcare, the owner of the registered trademark Clearasil®

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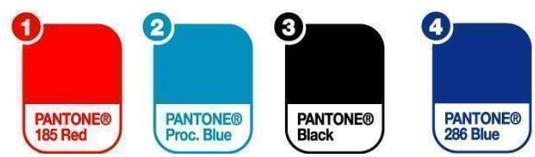
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Invisible Acne Cream



LEADER MAXIMUM STRENGTH INVISIBLE ACNE

benzoyl peroxide 10% cream

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:37205-279
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
ALUMINUM HYDROXIDE (UNII: 5QB0T2IUN0)	
CARBOMER HOMOPOLYMER TYPE C (UNII: 4Q93RCW27E)	
GLYCERYL MONOSTEARATE (UNII: 230OU9XXE4)	
ISOPROPYL MYRISTATE (UNII: 0RE8K4LNJS)	
MAGNESIUM ALUMINUM SILICATE (UNII: 6M3P64V0NC)	
METHYLPARABEN (UNII: A2I8C7HI9T)	
POLYETHYLENE GLYCOL 600 (UNII: NL4J9F21N9)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
PROPYLPARABEN (UNII: Z8IX2SC1OH)	
WATER (UNII: 059QF0K00R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:37205-279-10	1 in 1 CARTON		
1	NDC:37205-279-11	28 g in 1 TUBE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part333D	06/01/2008	

Labeler - Cardinal Health (097537435)**Registrant** - Lee Pharmaceuticals (056425432)**Establishment**

Name	Address	ID/FEI	Business Operations
Cardinal Health		097537435	label(37205-279)

Establishment

Name	Address	ID/FEI	Business Operations
Lee Pharmaceuticals		056425432	pack(37205-279)

Establishment

Name	Address	ID/FEI	Business Operations
Unipack		009248480	manufacture(37205-279)

