

CARADERMA- benzoyl peroxide cream
A Refreshing Discovery, 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.

CaraDerma acne treatment

Active ingredient

Benzoyl Peroxide 7.5%

Purpose

Acne Treatment

Use

for the management of acne

Warnings

For external use only

Do not use this medication if you have very sensitive skin or if you are sensitive to benzoyl peroxide.

Ask a doctor before use if you are using other topical acne medications at the same time or immediately following use of this product. This may increase dryness or irritation of the skin. If this occurs, only one medication should be used unless directed by a doctor.

When using this product

- Do not use in or near eyes. If contact occurs, rinse thoroughly with water.
- Keep away from lips and mouth.
- Avoid unnecessary sun exposure and use a sunscreen.

Stop use and ask a doctor if skin irritation occurs.

Keep out of reach of children. If swallowed, get medical help or contact a poison control center immediately.

Other information

This product may bleach hair or dyed fabrics. Store at 20-25°C (68-77°F).

Inactive ingredients

Aluminum Hydroxide, Bentonite, Carbomer Homopolymer Type C, Cetyl Alcohol, Diazolidinyl Urea, Glyceryl Monostearate, HEPES, Hydrocortisone, Isopropyl Myristate, Methylparaben, Phenacetin, Polyethylene Glycol, Propylene Glycol, Propylparaben, Sodium Benzoate, Water

Directions

- Cleanse the skin thoroughly before applying.
- Cover the entire affected area with a thin layer one to three times daily.
- Because excessive drying 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 going outside, use a sunscreen.
- Allow CaraDerma® to dry before applying sunscreen.
- If irritation or sensitivity develops, discontinue use and consult a doctor.

Package/Label Principal Display Panel

CaraDerma®

OOO acne treatment

anti-inflammatory properties

works on cystic acne

fast acting

For Moderate to Severe Acne

Works on All Skin Types

Active Ingredient:

Benzoyl Peroxide 7.5%

Net Wt: 1/2 oz. (15 grams)

Manufactured for

A Refreshing Discovery, Inc.

Raleigh, NC 27614

Made in the USA

CaraDerma®

○○○ acne treatment

NDC#51130-333-12

Drug Facts

Active Ingredient **Purpose**
Benzoyl Peroxide 7.5%...Acne Treatment

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Manufactured for
A Refreshing Discovery, Inc.
Raleigh, NC. 27614

- Fast Acting- Results are noticeable within the first 48 hours of treatment

- Made with FDA approved ingredients

- Does not have the negative side effects associated with hydrocortisone, such as retarding or stopping new skin cell growth.

- Invisible on skin, can be worn with make-up and sunscreens.

- Less Irritating

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Benzoyl Peroxide 7.5%

30 Day Money Back Guarantee.

Made in the USA

Net Wt: 1/2 oz. (15 grams)

UPC code



Carton Label

CARADERMA

benzoyl peroxide cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:51130-333
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
BENZOYL PEROXIDE (UNII: W9WZN9A0GM) (BENZOYL PEROXIDE - UNII:W9WZN9A0GM)	BENZOYL PEROXIDE	1.125 g in 15 g

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
GLYCERYL MONOSTEARATE (UNII: 230OU9XXE4)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
BENTONITE (UNII: A3N5ZCN45C)	
ISOPROPYL MYRISTATE (UNII: 0RE8K4LNJS)	
CETYL ALCOHOL (UNII: 936JST6JCN)	
HYDROCORTISONE (UNII: WI4X0X7BPJ)	
PHENACETIN (UNII: ER0CTH01H9)	
ALUMINUM HYDROXIDE (UNII: 5QB0T2IUN0)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	
METHYLPARABEN (UNII: A2I8C7HI9T)	
PROPYLPARABEN (UNII: Z8IX2SC1OH)	
POLYETHYLENE GLYCOL (UNII: 3WJQ0SDW1A)	
CARBOMER HOMOPOLYMER TYPE C (UNII: 4Q93RCW27E)	
DIAZOLIDINYL UREA (UNII: H5RIZ3MPW4)	
HYDROXYETHYLPIPERAZINE ETHANE SULFONIC ACID (UNII: RWW266YE9I)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:51130-333-12	1 in 1 CARTON		
1		15 g in 1 JAR		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333D	09/02/2010	

Labeler - A Refreshing Discovery, Inc. (604440243)

Establishment

Name	Address	ID/FEI	Business Operations
Advanced Skin Technologies Inc.		176084556	MANUFACTURE

Revised: 10/2010

A Refreshing Discovery, Inc.