# 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.

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### 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 O O oacne treatment

NDC#51130-333-12

### Drug Facts

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

Use for the management of acne

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Glyceryl Monostearate, Hepes,
Hydrocoftsone, Isopropyl Myristate,
Methylparaben, Phenacetin,
Polyethylene Glycol, Propylene
Glycol, Propylparaben,
Sodium Benzoate, Water

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Made in the USA

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

# CaraDerma O O oacne treatment

--- anti-inflammatory properties

--- works on cystic acne

----- fast acting

For Moderate to Severe Acne Works on All Skin Types

Active Ingredient: Benzovl Peroxide 7.5%

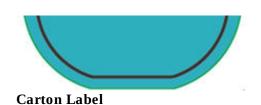
Net Wt: 1/2 oz. (15 grams)

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- If going outside, use a sunscreen.
- Allow CaraDerma\* to dry before applying sunscreen.
- If irritation or sensitivity develops, discontinue use and consult a doctor.

30 Day Money Back Guarantee.

UPC code



# CARADERMA

benzoyl peroxide cream

<b>Product Information</b>	n
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Product TypeHUMAN OTC DRUGItem Code (Source)NDC:51130-333

Route of Administration TOPICAL

# Active Ingredient/Active Moiety

Ingredient Name Basis of Strength Strength

BENZOYL PEROXIDE (UNII: W9 WZN9 A0 GM) (BENZOYL PEROXIDE - UNII: W9 WZN9 A0 GM) | BENZOYL PEROXIDE | 1.125 g in 15 g

Inactive Ingredients	
Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
GLYCERYL MONOSTEARATE (UNII: 230 O U9 XXE4)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
BENTONITE (UNII: A3N5ZCN45C)	
ISOPROPYL MYRISTATE (UNII: 0 RE8 K4LNJS)	
CETYL ALCOHOL (UNII: 936JST6JCN)	
HYDRO CORTISONE (UNII: WI4X0 X7BPJ)	
PHENACETIN (UNII: ER0 CTH0 1H9)	
ALUMINUM HYDRO XIDE (UNII: 5QB0T2IUN0)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	
METHYLPARABEN (UNII: A2I8C7HI9T)	
PROPYLPARABEN (UNII: Z8IX2SC1OH)	
POLYETHYLENE GLYCOL (UNII: 3WJQ0SDW1A)	
CARBOMER HOMOPOLYMER TYPE C (UNII: 4Q93RCW27E)	
DIAZO LIDINYL UREA (UNII: H5RIZ3MPW4)	
HYDRO XYETHYLPIPERAZINE ETHANE SULFONIC ACID (UNII: RWW266 YE91)	

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.