REVITOL ACNE TREATMENT- benzoyl peroxide cream
Revitol Corporation

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.....Purpose:

Benzoyl Peroxide 5%.....Acne Medication

Use:

For the treatment of acne.

Warnings:

For external use only.

Do not use

if you have sensitive skin or are sensitive to benzoyl peroxide.

When using this product:

- Avoid unnecessary sun exposure and use sunscreen.
- Keep away from eyes, lips and mouth areas.
- Using other topical acne drug at the same time or right after may increase dryness or irritation of skin. If this occurs, only one medication should be used unless directed by a doctor.
- Irritation may develop, such as redness, burning, itching, peeling or possibly swelling.
- It may bleach hair or dye fabrics.

Stop use and ask a doctor if

irritation becomes severe and continues

Keep out of reach of children.

if swallowed, get medical help or contact a Poison Control Center right away.

Directions:

- Cleanse the skin thoroughly before applying medication
- Cover the entire affected area with a thin layer one to three times a day
- Because excessive drying of the skin may occur, start with one application daily, then gradually increase to two ore three times daily if needed or as directed by a doctor. If bothersome drying or peeling occurs, reduce application to once a day or every other day.
- If going outside, use a sunscreen. Allow Acne Treatment Cream to dry, then follow directions in sunscreen labeling if sensitivity develops, discontinue use of both products and ask a doctor.

Other Information:

Enter section text here

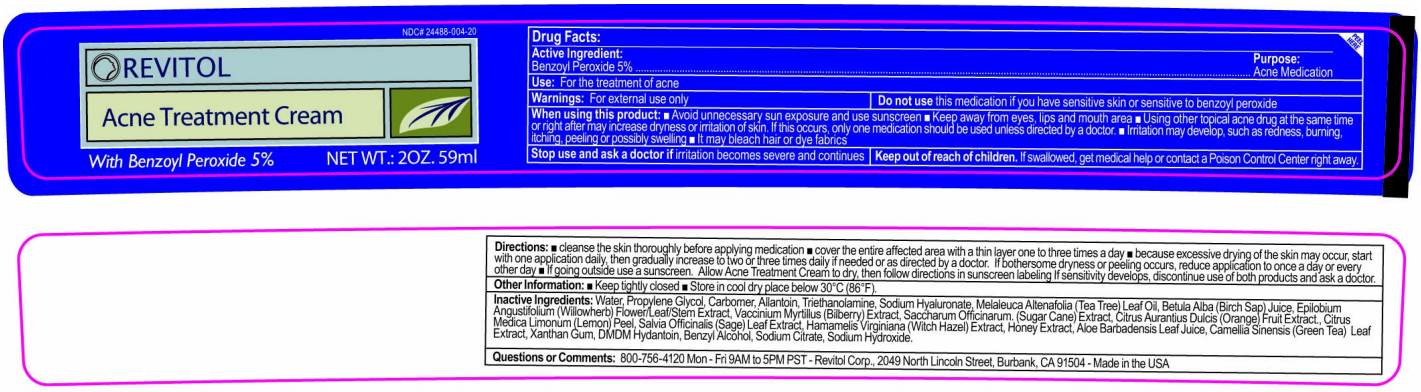
Inactive Ingredients

Water, Propylene Glycol, Carbomer Allantoin, Triethanolamine, Sodium Hyaluronate, Melaleuca Alternafolia (Tea Tree) Leaf Oil, Betula Alba (Birch Sap) Juice, Epilobium Angustifolium (Willowherb) Flower/Leaf/Stem Extract, Vaccinium Myrtillus (Bilberry) Extract, Saccharum Officinarum (Sugar Cane) Extract, Citrus Aurantius Dulcis (Orange) Fruit Extract, Citrus Medica Limonum (Lemon) Peel, Salvia Officinalis (Sage) Leaf Extract, Hamamelis Virginiana (Witch Hazel) Extract, Honey Extract, Aloe Barbadensis Leaf Juice, Camellia Sinensis (Green Tea) Leaf Extract, Xathan Gum, DMDM Hydantoin, Benzyl Alcohol, Sodium Citrate, Sodium Hydroxide

Questions or Comments:

1-800-756-4120 Mon - Fri 9AM to 5PM PST - Revitol Corp., 2049 North Lincoln Street, Burbank, CA 91504 - Made in the USA

Placeholder Text



5000 quantity

conicalized die line 6.8994″ by 0.7858″ to fit 2oz round jar.

REVITOL ACNE TREATMENT

benzoyl peroxide cream

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:24488-004
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
BENZOYL PEROXIDE (UNII: W9WZN9A0GM) (BENZOIC ACID - UNII:8SKN0B0MIM)	BENZOYL PEROXIDE	2.95 mL in 59 mL

Inactive Ingredients	
Ingredient Name	**Strength**
WATER (UNII: 059QF0KO0R)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
CARBOMER HOMOPOLYMER TYPE C (UNII: 4Q93RCW27E)	
ALLANTOIN (UNII: 344S277G0Z)	
TROLAMINE (UNII: 9O3K93S3TK)	
HYALURONATE SODIUM (UNII: YSE9PPT4TH)	
TEA TREE OIL (UNII: VIF565UC2G)	
BETULA PUBESCENS RESIN (UNII: 9G931M6I4G)	
EPILOBIUM ANGUSTIFOLIUM LEAF (UNII: 7NV86426N2)	
BILBERRY (UNII: 9P2U39H18W)	
SUGARCANE (UNII: 81H2R5AOH3)	
ORANGE (UNII: 5EVU04N5QU)	
LEMON PEEL (UNII: 72O054U628)	
SAGE (UNII: 065C5D077J)	
HAMAMELIS VIRGINIANA ROOT BARK/STEM BARK (UNII: T7S323PKJS)	
HONEY (UNII: Y9H1V576FH)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
GREEN TEA LEAF (UNII: W2ZU1RY8B0)	
XANTHAN GUM (UNII: TTV12P4NEE)	
DMDM HYDANTOIN (UNII: BYR0546TOW)	
BENZYL ALCOHOL (UNII: LKG8494WBH)	
SODIUM CITRATE (UNII: 1Q73Q2JULR)	
SODIUM HYDROXIDE (UNII: 55X04QC32I)	

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:24488-004-20	59 mL in 1 JAR		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333D	04/14/2011	

Labeler - Revitol Corporation (961956229)

Registrant - Creation's Garden Natural Products (961956229)

Establishment

Name	Address	ID/FEI	Business Operations
Creation's Garden Natural Products		961956229	manufacture

Revised: 4/2011 Revitol Corporation