

**BIO-SCRIPTIVES REPIDERM- benzoly peroxide cream**  
**BioChemics, 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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**Drug Facts**

**Active Ingredients**

4.4% Benzoyl Peroxide

**Purpose**

Acne Treatment

**Uses**

■ for the treatment of acne

**For external use only**

**Do not use if you**

- have very sensitive skin
- if you 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 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 ask a doctor if** ■ irritation becomes severe

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

**Directions**

■ clean the skin thoroughly before applying this product ■ cover the entire affected area with a thin layer one to three times daily ■ because excessive drying of the skin 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 bothersome dryness or peeling occurs, reduce application to once a day or every other day ■ if going outside, apply sunscreen after using this product. If irritation or sensitivity develops, stop use of both products and ask a doctor.

**Inactive Ingredients**

Distilled Water, Aloe, Propylene Glycol, Cetyl Alcohol, Glyceryl Monostearate, Arginine HCl, Dimethicone, Cyclomethicone, PEG-40 Hydrogenated Castor Oil, Coleus Forskohlii Oil, Lemon Oil, Melaleuca Alternifolia (Tea Tree) Leaf Oil, Eucalyptus Oil, Rosmarinus Officinalis (Rosemary) Leaf Oil, Sodium Chloride, Fragrance, Xanthan Gum, Allantoin, Calendula Officinalis Flower Extract,

Algae Extract, Althaea Officianalis Root Extract, Echinacea Augustifolia Extract, Chamomile Extract, Melia Azadirachta See Oil, Methylisothiazolinone, Sodium EDTA, Methyl Nicotinate.

BioScriptives™

77 N. Washington Street

Boston, MA 02114

617-379-5676

**LABEL**

**REPIDERM**  
*(Benzoyl Peroxide 4.4%)*

Acne Treatment  
Clears & Prevents Acne  
Derma-Release® Technology

bio+scriptives

NET Wt: 2 oz. (56g)

| <b>Drug Facts</b>  |                                     |
|--|-------------------------------------|
| <b>Active Ingredient</b>   | <b>Purpose</b>                      |
| Benzoyl peroxide 4.4%  | Acne treatment                      |
| <b>Use</b> ■ for the treatment of acne   |                                     |
| <b>Warnings</b>  |                                     |
| 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. |                                     |

Bio-Scriptives®  
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**Drug Facts (continued)**

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 ask a doctor if** ■ irritation becomes severe

**Keep out of reach of children.** If swallowed, get medical help or contact a Poison Control Center right away.

**Directions** ■ clean the skin thoroughly before applying this product ■ cover the entire affected area with a thin layer one to three times daily ■ because excessive drying of the skin may occur, start with one application daily, then gradually increase to

**Drug Facts (continued)**

two or three 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, apply sunscreen after using this product. If irritation or sensitivity develops, stop use of both products and ask a doctor

**Inactive ingredients** Distilled Water, Aloe, Propylene Glycol, Cetyl Alcohol, Glyceryl Stearate, Arginine HCl, Dimethicone, Cyclomethicone, PEG-40 Hydrogenated Castor Oil, Coleus Forskohlii Root Oil, Lemon Oil, Melaleuca Alternifolia (Tea Tree) Leaf Oil, Eucalyptus Oil, Rosmarinus Officinalis (Rosemary) Leaf Oil, Sodium Chloride, Fragrance, Xanthan Gum, Allantoin, Calendula Officinalis Flower Extract, Algae Extract, Althaea Officinalis Root Extract, Echinacea Angustifolia Extract, Chamomile Extract, Melia Azadirachta Seed Oil, Methylisothiazolinone, Sodium EDTA, Methyl Nicotinate.

**BIO-SCRIPTIVES REPIDERM**

benzoyl peroxide cream

**Product Information**

|                                |                |                           |               |
|--------------------------------|----------------|---------------------------|---------------|
| <b>Product Type</b>            | HUMAN OTC DRUG | <b>Item Code (Source)</b> | NDC:60608-012 |
| <b>Route of Administration</b> | TOPICAL        |                           |               |

**Active Ingredient/Active Moiety**

| Ingredient Name  | Basis of Strength | Strength       |
|--|-------------------|----------------|
| BENZOYL PEROXIDE (UNII: W9WZN9A0GM) (BENZOYL PEROXIDE - UNII:W9WZN9A0GM) | BENZOYL PEROXIDE  | 3.29 g in 56 g |

**Inactive Ingredients**

| Ingredient Name  | Strength |
|--|----------|
| water (UNII: 059QF0K00R)                               |          |
| ALOE VERA LEAF (UNII: ZY81Z83H0X)                      |          |
| PROPYLENE GLYCOL (UNII: 6DC9Q167V3)                    |          |
| CETYL ALCOHOL (UNII: 936JST6JCN)                       |          |
| GLYCERYL MONOSTEARATE (UNII: 230OU9XXE4)               |          |
| ARGININE HYDROCHLORIDE (UNII: F7LTH1E20Y)              |          |
| DIMETHICONE (UNII: 92RU3N3Y1O)                         |          |
| CYCLOMETHICONE (UNII: NMQ347994Z)                      |          |
| HYDROGENATED CASTOR OIL (UNII: ZF94AP8MEY)             |          |
| COLEUS FORSKOHLII ROOT OIL (UNII: 5NXR7DJ9WO)          |          |
| LEMON OIL (UNII: I9GRO824LL)                           |          |
| MELALEUCA ALTERNIFOLIA LEAF (UNII: G43C57162K)         |          |
| EUCALYPTUS OIL (UNII: 2R04ONI662)                      |          |
| ROSEMARY OIL (UNII: 8LGU7VM393)                        |          |
| SODIUM CHLORIDE (UNII: 451W47IQ8X)                     |          |
| XANTHAN GUM (UNII: TTV12P4NEE)                         |          |
| ALLANTOIN (UNII: 344S277G0Z)                           |          |
| AZADIRACHTIN (UNII: O4U1SAF85H)                        |          |
| ALTHAEA OFFICINALIS ROOT (UNII: TRW2FUF47H)            |          |
| CALENDULA OFFICINALIS FLOWERING TOP (UNII: 18E7415PXQ) |          |
| ASCOPHYLLUM NODOSUM (UNII: 168S4EO8YJ)                 |          |
| ECHINACEA ANGUSTIFOLIA (UNII: VB06AV5US8)              |          |
| CHAMOMILE (UNII: FGL3685T2X)                           |          |
| METHYLISOTHIAZOLINONE (UNII: 229D0E1QFA)               |          |
| EDETATE SODIUM (UNII: MP1J8420LU)                      |          |
| METHYL NICOTINATE (UNII: 7B1AVU9DJN)                   |          |

### Packaging

| # | Item Code        | Package Description       | Marketing Start Date | Marketing End Date |
|---|------------------|---------------------------|----------------------|--------------------|
| 1 | NDC:60608-012-00 | 56 g in 1 BOTTLE, PLASTIC |                      |                    |

### Marketing Information

| Marketing Category  | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|---------------------|--|----------------------|--------------------|
| OTC monograph final | part333D                                 | 07/24/2010           |                    |

**Labeler** - BioChemics, Inc. (802946426)

**Registrant** - Coastal Products Company (782445688)

### Establishment

| Name                     | Address | ID/FEI    | Business Operations    |
|--------------------------|---------|-----------|------------------------|
| Coastal Products Company |         | 782445688 | manufacture(60608-012) |

