

**BREAKOUT CLEARING EMERGENCY SPOT FIX- benzoyl peroxide lotion**  
**Dermologica, 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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**Breakout Clearing Emergency Spot Fix**

***Drug Facts***

**Active ingredient**

Benzoyl Peroxide (5.0%)

**Purpose**

Acne Treatment

**Use**

- For the treatment of acne

**Warnings**

**For external use only**

**Do not use**

- In or near eyes
- On broken skin
- On lips or large areas of the body
- If you have very sensitive skin
- If you are sensitive to benzoyl peroxide

**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.

**When using this product**

- Apply to affected areas only.
- Avoid unnecessary sun exposure and use sunscreen.
- This product may bleach hair or dyed fabrics.
- Skin irritation and dryness are more likely to occur if you use another topical acne medication at the same time. If irritation occurs, use only one topical acne medication at a time.

**Stop use and ask a physician**

- If too much skin irritation or sensitivity develops or increases.

**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.
- Cover the affected area with a thin layer 1 to 3 times a day.

- Because too much drying of the skin may occur, start with one application daily, and then gradually increase to 2 or 3 times daily if needed or as directed by a physician.
- If bothersome dryness or peeling occurs, reduce application to once a day or every other day.
- If going outside, use a sunscreen. Allow Emergency Spot Fix to dry, then follow directions of the sunscreen labeling.
- If irritation or sensitivity develops, stop use of both products and ask a doctor.

#### **Other information**

- Protect this product from excessive heat and direct sun.

#### **Inactive ingredients**

Water/Aqua/Eau, PEG-8, Camellia Sinensis Leaf Extract, Glycyrrhiza Glabra (Licorice) Root Extract, Porphyra Umbilicalis Extract, Enantia Chlorantha Bark Extract, Oleanolic Acid, Lavandula Angustifolia (Lavender) Extract, Melaleuca Alternifolia (Tea Tree) Leaf Oil, Spiraea Ulmaria Extract, Cetyl Alcohol, Sodium Acrylate/Sodium Acryloyl Dimethyl Taurate Copolymer, Polysorbate 80, Glyceryl Stearate, Caprylic/Capric Triglyceride, Ethylhexylglycerin, Butylene Glycol, Acrylates/C10-30 Alkyl Acrylate Crosspolymer, Aminomethyl Propanol, Xanthan Gum, Disodium EDTA, Phenoxyethanol.

#### **Questions or comments**

Call toll free 1-800-831-5150 in the US

#### **PRINCIPAL DISPLAY PANEL - 9 mL Tube Carton**

**dermalogica<sup>®</sup>**

**clear**

5%

benzoyl

peroxide

Breakout Clearing

**Emergency**

**Spot Fix**

0.3 US FL OZ / 9 mL e

Breakout Clearing  
**Emergency  
Spot Fix**

breakouts



dermalogica®  
**clear**  
start™

5%

benzoyl  
peroxide

Breakout Clearing  
**Emergency  
Spot Fix**

0.3 US FL OZ / 9 mL e

Clear Start is created by Dermalogica, the #1 professional skin care brand worldwide, to treat younger, breakout-prone skin.

Breakout Clearing  
**Emergency  
Spot Fix**



**Clears breakouts fast  
use at first sign of a breakout**

Dab this powerful concentrated gel directly onto individual breakouts: formula wipes out pimple-causing bacteria deep within the pore to clear your breakout fast.

Clear Start™ is tough on breakouts, gentle on your skin: potent active ingredients and naturally gentle botanicals deliver your clearest, healthiest skin ever.

- Benzoyl Peroxide kills breakout-causing bacteria deep within pores.
- Formulated with 7 gentle botanicals including Camellia Sinensis, Lavender and Tea Tree, known to calm skin irritation and redness.

We don't formulate with artificial fragrances, dyes or mineral oils. Get more great skin tips at [clearstart.com](http://clearstart.com).

[clearstart.com](http://clearstart.com)  
© Dermalogica, Inc.  
Dermalogica, Dist.  
Los Angeles, CA 90009 USA  
1-800-831-5150  
*Europe: London KT22 8JB UK*



Made in  
the USA

110840-00

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Emergency Peel Here Spot Fix

**Drug Facts**

**Active ingredient**  
Benzoyl Peroxide (5.0%)  
**Purpose**  
Acne Treatment

**dermatologica**

In the US  
Call toll free  
1-800-831-5150

**Questions or comments**

ethanol.  
Gum, Disodium EDTA, Phenoxy-  
Ammonium Propyl, Xanthan  
to this product.  
Benzoyl Peroxide, Acrylate/C10-  
Trihexylene, Ethylhexylglycerin,  
eryl Stearate, Caprylic/Capric  
polymer, Polyisobutyl Acrylate, Glyc-  
Acryloyl Dimethyl Taurate Co-  
hol, Sodium Acrylate/Sodium  
Ulmaria Extract, Cetyl Alco-  
(Tea Tree) Leaf Oil, Spiraea  
Extract, Melaleuca Alternifolia  
dida Angustifolia (Lavender)  
Extract, Oleandric Acid, Lavan-  
Extract, Embelia Chirantia Bark  
Extract, Peppermint Leaf Oil  
primula verba (Lemon) Root  
Water/Aqua/Eau, PEG-8, Carnel-

**Inactive ingredients**

and direct sun.  
from excessive heat.  
Protect this product

**Other information**

increase to 2 or 3  
times daily if needed  
or as directed by a  
physician.  
If bothersome  
dryness or peeling  
occurs, reduce  
application  
to once a day or  
every other day.  
If going outside, use  
a sunscreen. Allow  
to dry, then follow  
directions of the  
sunscreen labeling.  
If irritation or  
sensitivity develops,  
stop use of both  
products and ask a  
doctor.

**Drug Facts**  
(continued)

**Use**  
For the treatment  
of acne

**Warnings**  
For external use only

**Do not use**  
In or near eyes  
On broken skin  
On lips or large areas  
of the body  
If you have very  
sensitive skin  
If you are sensitive to  
benzoyl peroxide

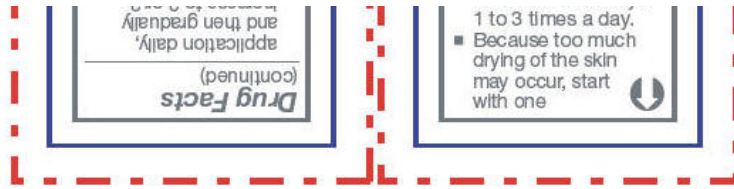
**Skin irritation may occur**, characterized  
by redness, burning,  
itching, peeling, or  
possibly swelling.  
Irritation may be  
reduced by using the  
product less  
frequently or in a lower  
concentration.

**When using this product**  
Apply to affected  
areas only.  
Avoid unnecessary  
sun exposure and  
use sunscreen.  
This product may  
bleach hair or dyed  
fabrics.  
Skin irritation and  
dryness are more  
likely to occur if you  
use another topical  
acne medication at  
the same time. If  
irritation occurs, use  
only one topical acne  
medication at a time.

**Stop use and ask a physician**  
If too much skin  
irritation or sensitivity  
develops or increases.

**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.  
Cover the affected  
area with a thin layer



## BREAKOUT CLEARING EMERGENCY SPOT FIX

benzoyl peroxide lotion

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:68479-202
<b>Route of Administration</b>	TOPICAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
<b>Benzoyl Peroxide</b> (UNII: W9WZN9A0GM) (Benzoyl Peroxide - UNII:W9WZN9A0GM)	Benzoyl Peroxide	50 mg in 1 mL

### Inactive Ingredients

Ingredient Name	Strength
<b>Water</b> (UNII: 059QF0KO0R)	
<b>Polyethylene Glycol 400</b> (UNII: B697894SGQ)	
<b>Green Tea Leaf</b> (UNII: W2ZU1RY8B0)	
<b>Glycyrrhiza Glabra</b> (UNII: 2788Z9758H)	
<b>Porphyra Umbilicalis</b> (UNII: 14AN0J70WO)	
<b>Annickia Chlorantha Bark</b> (UNII: H70115MP4A)	
<b>Oleanolic Acid</b> (UNII: 6SMK8R7TGJ)	
<b>Lavandula Angustifolia Flowering Top</b> (UNII: 9YT4B71U8P)	
<b>Tea Tree Oil</b> (UNII: VIF565UC2G)	
<b>Filipendula Ulmaria Root</b> (UNII: 997724QNDS)	
<b>Cetyl Alcohol</b> (UNII: 936JST6JCN)	
<b>Sodium Acrylate/Sodium Acryloyldimethyltaurate Copolymer (4000000 MW)</b> (UNII: 1DXE3F3OZX)	
<b>Polysorbate 80</b> (UNII: 6OZP39ZG8H)	
<b>Glyceryl Monostearate</b> (UNII: 230OU9XXE4)	
<b>Medium-Chain Triglycerides</b> (UNII: C9H2L21V7U)	
<b>Ethylhexylglycerin</b> (UNII: 147D247K3P)	
<b>Butylene Glycol</b> (UNII: 3XUS85K0RA)	
<b>Carbomer Interpolymer Type A (Allyl Sucrose Crosslinked)</b> (UNII: 59TL3WG5CO)	
<b>Aminomethylpropanol</b> (UNII: LU49E6626Q)	
<b>Xanthan Gum</b> (UNII: TTV12P4NEE)	
<b>Edetate Disodium</b> (UNII: 7FLD91C86K)	
<b>Phenoxyethanol</b> (UNII: HIE492ZZ3T)	

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
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1	NDC:68479-202-02	1 in 1 CARTON		
1		9 mL in 1 TUBE		
2	NDC:68479-202-00	2 mL in 1 POUCH		
<b>Marketing Information</b>				
<b>Marketing Category</b>	<b>Application Number or Monograph Citation</b>		<b>Marketing Start Date</b>	<b>Marketing End Date</b>
OTC MONOGRAPH FINAL	part333D		06/03/2013	

**Labeler** - Dermalogica, Inc. (177698560)

### Establishment

Name	Address	ID/FEI	Business Operations
Cosway		620899877	MANUFACTURE(68479-202)

### Establishment

Name	Address	ID/FEI	Business Operations
Diamond Wipes		161104729	MANUFACTURE(68479-202)

Revised: 2/2014

Dermalogica, Inc.