

**BREAKOUT CLEARING OVERNIGHT TREATMENT- salicylic acid 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 Overnight Treatment**

***Drug Facts***

**Active ingredient**

Salicylic Acid (2.0%).

**Indications**

- for the treatment of acne

**Warnings**

**For external use only.**

**Do not use**

- in or near eyes. If contact occurs, flush thoroughly with water

**When using this product**

- apply to affected areas only
- 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.

**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.
- Cover the affected area with a thin layer at night.
- Because too much drying of the skin may occur, start with 1 application daily at night, and if bothersome dryness or peeling occurs, reduce application to 2 to 3 times per week.

**Other information**

- Protect this product from excessive heat and direct sun.

**Inactive ingredients**

Water/Aqua/Eau, Isohexadecane, PEG-32, Glyceryl Stearate, Dimethicone, Hydroxyethyl Acrylate/Sodium Acryloyldimethyl Taurate Copolymer, Cetearyl Alcohol, Butylene Glycol, C12-15 Alkyl Benzoate, Stearic Acid, Melaleuca Alternifolia (Tea Tree) Leaf Oil, Spiraea Ulmaria Extract, Camphor, Lavandula Angustifolia (Lavender) Flower Extract, Camellia Sinensis Leaf Extract, Glycyrrhiza Glabra Rhizome/Root, Porphyra Umbilicalis Extract, Cucumis Sativus (Cucumber) Fruit Extract, Sodium Hyaluronate Crosspolymer, Caprylic/ Capric Triglyceride, Zinc Acetate, Potassium Jojobate, Propanediol, PVM/ MA Copolymer, Cetareth-20, Xanthan Gum, Polysorbate 60, Jojoba

Alcohol, Sodium Hydroxide, Ethylhexylglycerin, Phenoxyethanol.

**Questions or comments**

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

**PRINCIPAL DISPLAY PANEL - 59 mL Tube Carton**

**dermalogica<sup>®</sup>**

**clear**

**2%**

**salicylic**

**acid**

Breakout Clearing

**Overnight**

**Treatment**

2.0 US FL OZ / 59 mL e

Breakout Clearing  
**Overnight  
Treatment**

breakouts



dermalogica<sup>®</sup>

**clear**

start<sup>™</sup>

2%

salicylic  
acid

Breakout Clearing

Breakout Clearing

# Overnight Treatment

2.0 US FL OZ / 59 mL e

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

## Breakout Clearing Overnight Treatment



**Clears breakouts while you sleep use nightly for extra clearing**

Wake up to clearer skin! This invisible treatment absorbs quickly then works all night to fight breakouts. Rest easy as it purifies to ensure you awake with less congestion, fewer breakouts and reduced redness.

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

- Salicylic Acid prevents breakouts by naturally unclogging the follicle.
- Cooling Cucumber and soothing Licorice are known to help lull redness away.
- Unique botanicals including Tea Tree, Lavender and Camellia Sinensis are known to keep overactive oils in check.

We don't formulate with artificial fragrances

### Drug Facts (continued)

- 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.

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

<p><b>Drug Facts</b></p> <p><b>Active ingredient</b> Salicylic Acid (2.0 %).</p> <p><b>Indications</b> ■ for the treatment of acne</p> <p><b>Warnings</b> For external use only.</p> <p><b>Do not use</b> ■ in or near eyes. If contact occurs, flush thoroughly with water</p> <p><b>When using this product</b> ■ apply to affected areas only</p>
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Acryloyldimethyl Taurate Copolymer, Cetearyl Alcohol, Butylene Glycol, C12-15 Alkyl Benzoate, Stearic Acid, Melaleuca Alternifolia (Tea Tree) Leaf Oil, Spiraea Ulmaria Extract, Camphor, Lavandula Angustifolia (Lavender) Flower Extract, Camellia Sinesis Leaf Extract, Glycyrrhiza Glabra Rhizome/Root, Porphyra Umbilicalis Extract, Cucumis Sativus (Cucumber) Fruit Extract, Sodium Hyaluronate Crosspolymer, Caprylic/ Capric Triglyceride, Zinc Acetate, Potassium Jojobate, Propanediol, PVM/ MA Copolymer, Ceteareth-20, Xanthan Gum, Polysorbate 60, Jojoba Alcohol, Sodium Hydroxide, Ethylhexylglycerin, Phenoxyethanol.

**Questions or comments**  
Call toll free 1-800-831-5150 in the US

[clearstart.com](http://clearstart.com)  
© Dermalogica, Inc.  
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1-800-831-5150  
Europe: London KT22 8JB UK



Made in the USA

(D1313-00)



## BREAKOUT CLEARING OVERNIGHT TREATMENT

salicylic acid lotion

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:68479-313
<b>Route of Administration</b>	TOPICAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
Salicylic Acid (UNII: O414PZ4LPZ) (Salicylic Acid - UNII:O414PZ4LPZ)	Salicylic Acid	20 mg in 1 mL

## Inactive Ingredients

Ingredient Name	Strength
Water (UNII: 059QF0K00R)	
Isohexadecane (UNII: 918X1OUF1E)	
POLYETHYLENE GLYCOL 1500 (UNII: 1212Z7S33A)	
Glyceryl Monostearate (UNII: 230OU9XXE4)	
Dimethicone (UNII: 92RU3N3Y1O)	
HYDROXYETHYL ACRYLATE/SODIUM ACRYLOYLDIMETHYL TAURATE COPOLYMER (45000 MPa.S AT 1%) (UNII: 86FQE96TZ4)	
Cetostearyl Alcohol (UNII: 2DMT128M1S)	
Butylene Glycol (UNII: 3XUS85K0RA)	
Alkyl (C12-15) Benzoate (UNII: A9EJ3J61HQ)	
Stearic Acid (UNII: 4ELV7Z65AP)	
Tea Tree Oil (UNII: VIF565UC2G)	
FILIPENDULA ULMARIA ROOT (UNII: 997724QNDS)	
CAMPHOR (SYNTHETIC) (UNII: 5TJD82A1ET)	
Lavandula Angustifolia Flower (UNII: 19AHIRAF4M)	
Green Tea Leaf (UNII: W2ZU1RY8B0)	
GLYCYRRHIZA GLABRA (UNII: 2788Z9758H)	
Porphyra Umbilicalis (UNII: 14AN0J70WO)	
Cucumber (UNII: YY7C30VXJT)	
Medium-Chain Triglycerides (UNII: C9H2L21V7U)	
Zinc Acetate (UNII: FM5526K07A)	
Propanediol (UNII: 5965N8W85T)	
Polyoxyl 20 Cetostearyl Ether (UNII: YRC528SWUY)	
Xanthan Gum (UNII: TTV12P4NEE)	
Polysorbate 60 (UNII: CAL22UVI4M)	
Sodium Hydroxide (UNII: 55X04QC32I)	
Ethylhexylglycerin (UNII: 147D247K3P)	
Phenoxyethanol (UNII: HIE492ZZ3T)	

## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:68479-313-02	1 in 1 CARTON		
1		59 mL in 1 TUBE		
2	NDC:68479-313-01	14 mL in 1 TUBE		
3	NDC:68479-313-00	2 mL in 1 POUCH		

## Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH FINAL	part358H	09/06/2013	

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

## Establishment

<b>Name</b>	<b>Address</b>	<b>ID/FEI</b>	<b>Business Operations</b>
Cosway		620899877	MANUFACTURE(68479-313)

## **Establishment**

<b>Name</b>	<b>Address</b>	<b>ID/FEI</b>	<b>Business Operations</b>
Diamond Wipes		161104729	MANUFACTURE(68479-313)

Revised: 2/2014

Dermalogica, Inc.