

OVERNIGHT CLEARING- salicylic acid gel
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.

Overnight Clearing Gel

Drug Facts

Active Ingredients

Salicylic Acid 2.0%

Indications

- For the treatment of acne.

Warnings

For external use only.

Do not use on broken skin or on large areas of the body.

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.

Avoid unnecessary sun exposure and use a sunscreen.

Do not use in or near eyes.

Stop use and ask a Doctor if rash occurs.

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.

Inactive ingredients

Water (Aqua), PEG-32, Butylene Glycol, Salicylic Acid, PVM/MA Decadiene Crosspolymer, Polysorbate 20, Glycerin, PEG-60 Almond Glycerides, Mahonia Aquifolium Root Extract, Rosmarinus Officinalis (Rosemary) Leaf Extract, Camellia Oleifera Leaf Extract, Spiraea Ulmaria Extract, Aesculus Hippocastanum (Horse Chestnut) Seed Extract, Crithmum Maritimum Extract, Yeast Extract, Hydrogenated Vegetable Oil, Sodium Hyaluronate, Biotin, Panthenol, Caffeine, Niacinamide, Dipotassium Glycyrrhizate, Camphor, 10-Hydroxydecanoic Acid, Sebacic Acid, 1,10-Decanediol, Nordihydroquaiaretic Acid, Oleanolic Acid, Xanthan Gum, Carbomer, PEG-40 Hydrogenated Castor Oil, Ammonium Glycyrrhizate, Zinc Gluconate, Zinc Acetate, Sodium Hydroxide, Caprylic/Capric

Triglyceride, Chlorphenesin, Caprylyl Glycol, Phenoxyethanol, Limonene, Linalool, Geraniol, Melaleuca Alternifolia (Tea Tree) Leaf Oil, Rosmarinus Officinalis (Rosemary) Leaf Oil, Cymbopogon Martini Oil, Mentha Piperita (Peppermint) Oil, Citrus Grandis (Grapefruit) Peel Oil, Citrus Limon (Lemon) Peel Oil, Foeniculum Vulgare (Fennel) Oil, Mentha Viridis (Spearmint) Leaf Oil, Pelargonium Graveolens Flower Oil, Eucalyptus Globulus Leaf Oil, Zingiber Officinale (Ginger) Root Oil, Artemisia Vulgaris Oil, Litsea Cubeba Fruit Oil, Piper Nigrum (Pepper) Seed Oil, Myristica Fragrans (Nutmeg) Kernel Oil, Ocimum Basilicum (Basil) Oil, Cymbopogon Nardus (Citronella) Oil, Cinnamomum Zeylanicum Bark Oil, Citrus Aurantium Dulcis (Orange) Peel Oil, Lavandula Angustifolia (Lavender) Oil, Salvia Officinalis (Sage) Oil, Thymus Vulgaris (Thyme) Oil.

Questions or comments

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

PRINCIPAL DISPLAY PANEL - 50 mL Bottle Carton

overnight

clearing

gel

acne treatment

mediBac clearing®

1.7 US FL OZ

50 mL e

dermalogica®

overnight clearing gel

Nighttime gel helps clear skin and prevent future breakouts. Smooth over skin after cleansing at night. Salicylic Acid sloughs off pore-clogging skin cells to inhibit development of further breakouts, while naturally-antiseptic Tea Tree Oil soothes while you sleep. Helps inhibit breakout-causing bacteria with Meadowsweet (Spiraea Ulmaria) for clearer, healthier skin. Niacinamide and Biotin, combined with Zinc Gluconate, Yeast Extract, Caffeine and Licorice, help soothe away irritation.

Formulated without artificial fragrances, colors or parabens. Product guaranteed when professionally recommended.

© Dermalogica, Inc.
Dermalogica, Dist.
Los Angeles, CA 90009 USA
1-800-831-5150
Europe: London, KT22 8JR, UK



Made in the USA

dermalogica
dermalogica.com

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overnight clearing gel

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acne treatment

mediBac clearing®

1.7 US FL OZ
50 mL e

dermalogica®

a skin care system researched and developed by The International Dermal Institute

Drug Facts (continued)

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Questions or comments

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(3647-06)

1061 12-02



OVERNIGHT CLEARING

salicylic acid gel

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:68479-706
Route of Administration	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)	
Polyethylene Glycol 1500 (UNII: 1212Z7S33A)	
Butylene Glycol (UNII: 3XUS85K0RA)	
Polysorbate 20 (UNII: 7T1F30V5YH)	
Glycerin (UNII: PDC6A3C0OX)	
PEG-60 Almond Glycerides (UNII: 4Y0E651N0F)	
BERBERIS AQUIFOLIUM ROOT (UNII: 746TB9VNDP)	
Rosemary (UNII: IJ67X351P9)	
Camellia Oleifera Leaf (UNII: 5077EL0C60)	
Filipendula Ulmaria Root (UNII: 997724QNDS)	
Horse Chestnut (UNII: 3C18L6RJAZ)	
Crithmum Maritimum (UNII: J7IH79BKY)	
Yeast, Unspecified (UNII: 3NY3SM6B8U)	
Hyaluronate Sodium (UNII: YSE9PPT4TH)	
Biotin (UNII: 6SO6U10H04)	
Panthenol (UNII: WV9CM0O67Z)	
Caffeine (UNII: 3G6A5W338E)	
Niacinamide (UNII: 25X51I8RD4)	
Glycyrrhizinate Dipotassium (UNII: CA2Y0FE3FX)	
Camphor (Synthetic) (UNII: 5TJD82A1ET)	
10-Hydroxydecanoic Acid (UNII: NP03XO416B)	
Sebacic Acid (UNII: 97AN39ICTC)	
1,10-Decanediol (UNII: 5I577UDK52)	
Masoprocol (UNII: 7BO8G1BYQU)	
Oleanolic Acid (UNII: 6SMK8R7TGJ)	
Xanthan Gum (UNII: TTV12P4NEE)	
Carbomer Homopolymer Type C (Allyl Pentaerythritol Crosslinked) (UNII: 4Q93RCW27E)	
Polyoxyl 40 Hydrogenated Castor Oil (UNII: 7YC686GQ8F)	
Ammonium Glycyrrhizate (UNII: 3VRD35U26C)	
Zinc Gluconate (UNII: U6WSN5SQ1Z)	
Zinc Acetate (UNII: FM5526K07A)	
Sodium Hydroxide (UNII: 55X04QC32I)	
Medium-Chain Triglycerides (UNII: C9H2L21V7U)	
Chlorphenesin (UNII: I670DAL4SZ)	
Caprylyl Glycol (UNII: 00YIU5438U)	
Phenoxyethanol (UNII: HIE492ZZ3T)	

Tea Tree Oil (UNII: VIF565UC2G)
Rosemary Oil (UNII: 8LGU7VM393)
Palmarosa Oil (UNII: 0J3G3O53ST)
Peppermint Oil (UNII: AV092KU4JH)
Citrus Maxima Fruit Rind Oil (UNII: 8U3877WD44)
Lemon Oil (UNII: I9GRO824LL)
Fennel Oil (UNII: 59AAO5F6HT)
Spearmint Oil (UNII: C3M81465G5)
Pelargonium Graveolens Flower Oil (UNII: 3K0J1S7QGC)
Eucalyptus Oil (UNII: 2R04ON1662)
Ginger Oil (UNII: SAS9Z1SVUK)
Artemisia Vulgaris Top Oil (UNII: 72Q967Y48V)
Litsea Oil (UNII: 2XIW34BN6O)
White Pepper Oil (UNII: 2AM83DL9FV)
Nutmeg Oil (UNII: Z1CLM48948)
Basil Oil (UNII: Z129UMU8LE)
Citronella Oil (UNII: QYO8Q067D0)
Cinnamon Bark Oil (UNII: XE54U569EC)
Orange Oil (UNII: AKN3KSD11B)
Lavender Oil (UNII: ZBP1YXW0H8)
Sage Oil (UNII: U27K0H1H2O)
Thyme Oil (UNII: 2UK410MY6B)

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:68479-706-02	1 in 1 CARTON	05/01/2007	
1		50 mL in 1 BOTTLE; Type 0: Not a Combination Product		
2	NDC:68479-706-01	14 mL in 1 BOTTLE; Type 0: Not a Combination Product	05/01/2007	
3	NDC:68479-706-00	2 mL in 1 POUCH; Type 0: Not a Combination Product	05/01/2007	

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH FINAL	part358H	05/01/2007	

Labeler - Dermalogica, Inc. (177698560)

Establishment

Name	Address	ID/FEI	Business Operations
McKenna		090631412	MANUFACTURE(68479-706)

Establishment

Name	Address	ID/FEI	Business Operations
Diamond Wipes		161104729	MANUFACTURE(68479-706)

