

**SMART RELEASE MANDELIC 8 PERCENT- salicylic acid gel**  
**SkinClinical AI, LLC**

*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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**Smart Release Mandelic 8%**

**ACTIVE INGREDIENT**

SALICYLIC ACID .5%

**PURPOSE**

TREATMENT OF ACNE

**USE**

FOR THE TREATMENT OF ACNE

**WARNINGS**

For External Use 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 1 topical acne medication at a time.

**OTHER INFORMATION**

Keep tightly closed.

Protect from excessive heat (40°/ 140° F) and protect from freezing.

Stop use and ask a doctor if irritation or sensitivity develops.

Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away. This product contains Mandelic Acid that may increase your skin's sensitivity to the sun and the possibility of sunburn. Use a sunscreen, wear protective clothing and limit exposure to the sun using this product and for one week after you stop. Store at room temperature.

**DIRECTIONS**

Important to use on a clean face, Cover the affected area with a thin layer 1 to 3 times per day. Because of excessive drying of the skin may occur, start with 1 application per day then gradually increase to 2 applications per day, one morning and one evening if needed, or as directed by a doctor. If dryness or peeling occurs, reduce use to once a day or once every other day. If going outside, use a sunscreen. If irritation or sensitivity develops stop using both products and ask a doctor.

**INACTIVE INGREDIENTS**

Water (Agua), SD Alcohol 40-B, Mandelic Acid, Butylene Glycol, Hamamelis Virginiana (Witch Hazel) Leaf Water, Lactobacillus Ferment, PEG-8 SMDI Copolymer, Niacinamide, Lactic Acid, Sodium PCA, Sodium Lactate, Hydrolyzed Algin, Zinc Sulfate, Glycerin, Opuntia Ficus Indica (Nopal Cactus),

Saccharomyces Cerevisiae (Yeast) Extract, Hydroxyethylcellulose, Vaccinium Myrtillus Fruit Extract, Saccharum Officinarum (Sugar Cane) Extract, Acer Saccharum (Sugar Maple) Extract, Citrus Aurantium Dulcis (Orange) Fruit Extract, Citrus Limon (Lemon) Fruit Extract, Citrus Aurantium Bergamia (Bergamot) Fruit Oil, Citrus Grandis (Grapefruit) Peel Oil, Citrus Aurantium Dulcis (Orange) Peel Oil, Citrus Tangerina (Tangerine) Peel Oil



Top Ply

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**Inactive Ingredients:** Water (Aqua), SD Alcohol 40-B, Mandelic Acid, Butylene Glycol, Hamamelis Virginiana (Witch Hazel) Leaf Water, Lactobacillus Ferment, PEG-8 SMDI Copolymer, Niacinamide, Lactic Acid, Sodium PCA, Sodium Lactate, Hydrolyzed Algin, Zinc Sulfate, Glycerin, Opuntia Ficus Indica (Nopal Cactus), Saccharomyces Cerevisiae (Yeast) Extract, Hydroxyethylcellulose, Vaccinium Myrtillus Fruit Extract, Saccharum Officinarum (Sugar Cane) Extract, Acer Saccharum (Sugar Maple) Extract, Citrus Aurantium Dulcis (Orange) Fruit Extract, Citrus Limon (Lemon) Fruit Extract, Citrus Aurantium Bergamia (Bergamot) Fruit Oil, Citrus Grandis (Grapefruit) Peel Oil, Citrus Aurantium Dulcis (Orange) Peel Oil, Citrus Tangerina (Tangerine) Peel Oil

**Questions?**  
Call toll-free T. 1-800-200-6385 or visit [www.acneintelligence.com](http://www.acneintelligence.com)

**DRUG FACTS**

Active Ingredients	Purpose
Salicylic Acid .5%	Treatment of Acne

**USE:** For the treatment of acne.

**WARNINGS**  
For External Use Only.  
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If irritation occurs, only use 1 topical acne medication at a time.

**Other information:** Keep tightly closed. Protect from excessive heat (40°/140°F) and protect from freezing.

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## SMART RELEASE MANDELIC 8 PERCENT

salicylic acid gel

### Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:73110-103
Route of Administration	TOPICAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
SALICYLIC ACID (UNII: O414PZ4LPZ) (SALICYLIC ACID - UNII:O414PZ4LPZ)	SALICYLIC ACID	0.5 g in 100 mL

### Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0K00R)	

ALCOHOL (UNII: 3K9958V90M)
MANDELIC ACID (UNII: NH496X0UJX)
BUTYLENE GLYCOL (UNII: 3XUS85K0RA)
WITCH HAZEL (UNII: 101I4J0U34)
LACTOBACILLUS REUTERI (UNII: 9913I24QEE)
PEG-8/SMDI COPOLYMER (UNII: CCX72L6NY6)
NIACINAMIDE (UNII: 25X51I8RD4)
LACTIC ACID (UNII: 33X04XA5AT)
SODIUM PYRROLIDONE CARBOXYLATE (UNII: 469OTG57A2)
SODIUM LACTATE (UNII: TU7HW0W0QT)
SODIUM ALGINATE (UNII: C269C4G2ZQ)
ZINC SULFATE (UNII: 89DS0H96TB)
GLYCERIN (UNII: PDC6A3C0OX)
OPUNTIA FICUS-INDICA (UNII: 23Z87HTQ6P)
YEAST, UNSPECIFIED (UNII: 3NY3SM6B8U)
HYDROXYETHYL CELLULOSE (100 MPA.S AT 2%) (UNII: R33S7TK2EP)
BILBERRY (UNII: 9P2U39H18W)
SACCHARUM OFFICINARUM WHOLE (UNII: 3Z20C92XNB)
ORANGE (UNII: 5EVU04N5QU)
LEMON (UNII: 24RS0A988O)
BERGAMOT OIL (UNII: 39W1PKE3JJ)
CITRUS MAXIMA FRUIT RIND OIL (UNII: 8U3877WD44)
ORANGE OIL (UNII: AKN3KSD11B)
MANDARIN OIL (UNII: NJO720F72R)

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:73110-103-11	30 mL in 1 BOTTLE, DISPENSING; Type 0: Not a Combination Product	02/16/2019	

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part333D	02/16/2019	

**Labeler** - SkinClinical AI, LLC (116981342)

**Registrant** - SkinClinical AI, LLC (116981342)