

SMART RELEASE MANDELIC 11 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.

Smart Release Mandelic 11%

ACTIVE INGREDIENT

SALICYLIC ACID .5%

PURPOSE

TREATMENT OF ACNE

WARNINGS

For External Use Only.

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 1 topical acne medication at a time.

Avoid unnecessary sun exposure and use a sunscreen.

USE

HELPS PREVENT SUNBURN. IF USED WITH OTHER SUN PROTECTION MEASURES (SEE DIRECTIONS) DECREASES THE CHANCES OF SKIN CANCER AND EARLY SIGNES OF SKIN AGING CAUSED BY THE SUN.

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.

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

Questions?

Call toll-free T 1-800-200-6365 or visit www.acneintelligencellnce.com



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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

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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.
- Avoid unnecessary sun exposure and use a sunscreen.

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

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SMART RELEASE MANDELIC 11 PERCENT

salicylic acid gel

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:73110-104
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: 059QF0KO0R)	
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:73110-104-11	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)