SALICYLIC SERUM 1 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.

SALICYLIC SERUM 1%

ACTIVE INGREDIENT

SALICYLIC ACID 1%

PURPOSE

TREATMENT OF ACNE

USE

For the 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.

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

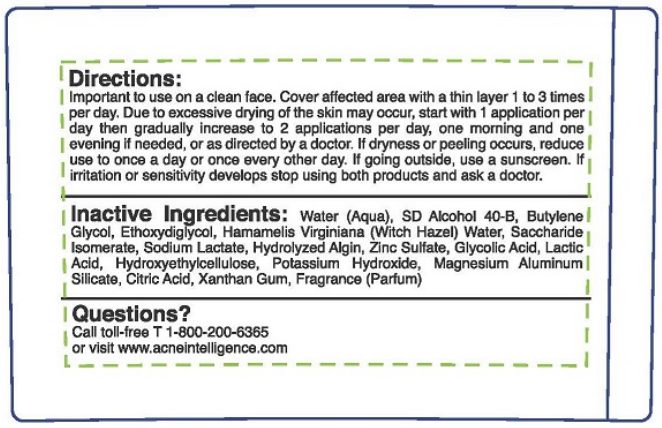
Important to use on a clean face. Cover affected area with a thin layer 1 to 3 times per day. Due to excessive drying of the skin may occur, start with 1 application per day then gradually increase to 2 applications per day, one morning and one evening if needed, or as directed by a doctor. If dryness 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.

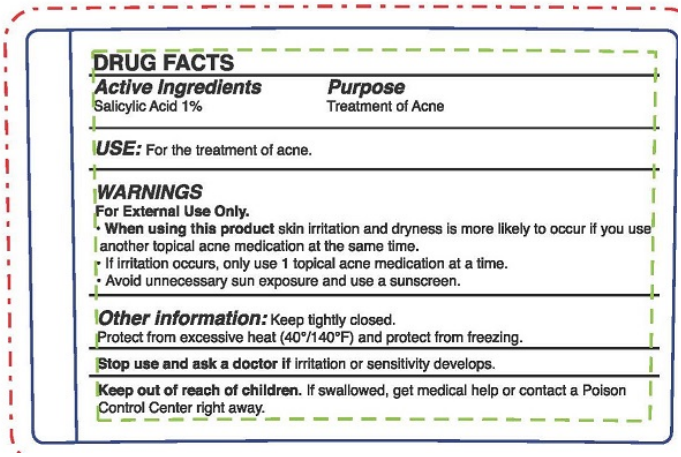
INACTIVE INGREDIENTS

Water (Aqua), SD Alcohol 40-B, Butylene Glycol, Ethoxydiglycol, Hamamelis Virginiana (Witch Hazel) Water, Saccharide lsomerate, Sodium Lactate, Hydrolyzed Algin, Zinc Sulfate, Glycolic Acid, Lactic Acid, Hydroxyethylcellulose, Potassium Hydroxide, Magnesium Aluminum Silicate, Citric Acid, Xanthan Gum, Fragrance (Parfum)

QUESTIONS?

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





SALICYLIC SERUM 1 PERCENT

salicylic acid gel

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:73110-101
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
SALICYLIC ACID (UNII: O414PZ4LPZ) (SALICYLIC ACID - UNII:O414PZ4LPZ)	SALICYLIC ACID	1 g in 100 mL

Inactive Ingredients	
Ingredient Name	**Strength**
BUTYLENE GLYCOL (UNII: 3XUS85K0RA)	
DIETHYLENE GLYCOL MONOETHYL ETHER (UNII: A1A1I8X02B)	

SACCHARIDE ISOMERATE (UNII: W8K377W98I)	
SODIUM LACTATE (UNII: TU7HW0W0QT)	
SODIUM ALGINATE (UNII: C269C4G2ZQ)	
ZINC SULFATE (UNII: 89DS0H96TB)	
LACTIC ACID (UNII: 33X04XA5AT)	
POTASSIUM HYDROXIDE (UNII: WZH3C48M4T)	
XANTHAN GUM (UNII: TTV12P4NEE)	
GLYCOLIC ACID (UNII: 0WT12SX38S)	
MAGNESIUM ALUMINUM SILICATE (UNII: 6M3P64V0NC)	
ANHYDROUS CITRIC ACID (UNII: XF417D3PSL)	
WATER (UNII: 059QF0KO0R)	
ALCOHOL (UNII: 3K9958V90M)	
WITCH HAZEL (UNII: 101I4J0U34)	
HYDROXYETHYL CELLULOSE (100 MPA.S AT 2%) (UNII: R33S7TK2EP)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:73110-101-11	30 mL in 1 BOTTLE, DISPENSING; Type 0: Not a Combination Product	05/10/2019	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part333D	05/10/2019	

Labeler - SkinClinical AI, LLC (116981342)

Registrant - SkinClinical AI, LLC (116981342)

Revised: 5/2019 SkinClinical AI, LLC