

SALICYLIC GEL- salicylic acid gel
Malin and Goetz 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.

salicylic gel

Active Ingredient Purpose

Salicylic Acid 2%-----Acne Treatment

Uses

For external use only

Keep out of reach of children.

If swallowed, get medical help or contact a Poison Control Center right away.

Warnings:

For external use only.

When using this product

Avoid contact with eyes. If contact occurs, immediately flush with water.

Directions

- Clean the skin thoroughly before applying this product
- Cover the entire affected area with a thin layer one to three times daily.
- Because excessive drying of the skin may occur, start with one application daily, then gradually increase to two or three times daily if needed or as directed by a doctor.
- If bothersome dryness or peeling occurs, reduce application to once a day or every other day.

Inactive ingredients

Water/Aqua/Eau, Alcohol Denat., Glycerin, Lactic Acid, Hydroxyethylcellulose, Sodium Hydroxide, Centella Asiatica Extract, Niacinamide, Phenoxyethanol, Salix Alba (Willow) Bark Extract, Citrus Aurantium Dulcis (Orange) Peel Oil, Disodium EDTA, Xanthan Gum, Mentha Piperita (Peppermint) Oil, Artemisia Absinthum Oil, Mentha Viridis (Spearmint) Leaf Oil, Tagetes Minuta Flower Oil, Achillea Millefolium Flower Extract.

Other Information

Protect the product in this container from excessive heat and direct sun.

Using other topical acne drugs at the same time or right after use of this product may increase dryness or irritation of the skin. If this occurs, only one drug should be used unless directed by a doctor.

(MALIN+GOETZ)

salicylic gel.

2% Salicylic Acid. Acne Gel

Daytime Treatment

0.5fl.oz./15ml

Drug Facts

Active Ingredient Purpose
Salicylic Acid 2%...Acne Treatment

Uses • For the treatment of acne.

Warnings: For external use only. Using other topical acne drugs at the same time or right after use of this product may increase dryness or irritation of the skin. If this occurs, only one drug should be used unless directed by a doctor. **When using this product:** • Avoid contact with eyes. If contact occurs, immediately flush with water. • 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 this product.
• Cover the entire affected area with a thin layer one to three times daily.
• Because excessive drying of the skin may occur, start with one application daily, then gradually increase to two or three times daily if needed or as directed by a doctor.
• If bothersome dryness or peeling occurs, reduce application to once a day or every other day.

Inactive Ingredients
Water/Aqua/Eau, Alcohol Denat., Glycerin, Lactic Acid, Hydroxyethylcellulose, Sodium Hydroxide, Camellia Asiatica Extract, Niacinamide, Phenoxyethanol, Salix Alba (Willow) Bark Extract, Citrus Aurantium Dulcis (Orange) Peel Oil, Disodium EDTA, Xanthan Gum, Mentha Piperita (Peppermint) Oil, Artemisia Absinthium Oil, Mentha Viridis (Spearmint) Leaf Oil, Tagetes Minuta Flower Oil, Achillea Millefolium Flower Extract.

Drug Facts (continued)

Other Information
• Protect the product in this container from excessive heat and direct sun.

(MALIN+GOETZ)

salicylic gel.

2% SALICYLIC ACID. ACNE GEL.
DAYTIME TREATMENT—AT-130-14.

0.5fl.oz./15ml

OUR EFFECTIVE SALICYLIC GEL TREATMENT IS FORMULATED WITH ACTIVE SALICYLIC ACID TO EFFECTIVELY TREAT BLEMISHES AND GLYCERIN TO MOISTURIZE. TRANSLUCENT GEL FORMULA MAKES IT IDEAL TO USE DURING DAYTIME; EVEN UNDER MAKEUP. NATURAL FRAGRANCE AND COLOR. DISTRIBUTED BY: MALIN+GOETZ INC., 330 SEVENTH AVENUE, NEW YORK, NY 10001, TEL. +1 212 244 7771, WWW.MALINANDGOETZ.COM. MADE IN USA. (MALIN+GOETZ)[®]



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SALICYLIC GEL

salicylic acid gel

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:53634-153
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
SALICYLIC ACID (UNII: O414PZ4LPZ) (SALICYLIC ACID - UNII:O414PZ4LPZ)	SALICYLIC ACID	2 g in 100 mL

Inactive Ingredients

Ingredient Name	Strength
SALIX ALBA BARK (UNII: 205MXS71H7)	
PHENOXYETHANOL (UNII: H1E492Z3T)	
EDETATE DISODIUM ANHYDROUS (UNII: 8NLQ36F6MM)	

XANTHAN GUM (UNII: TTV12P4NEE)
PEPPERMINT OIL (UNII: AV092KU4JH)
TAGETES MINUTA FLOWER OIL (UNII: 1T0ZMU8M8B)
CENTELLA ASIATICA TRITERPENOIDS (UNII: 4YS74Q4G4J)
ORANGE OIL, COLD PRESSED (UNII: AKN3KSD11B)
LACTIC ACID (UNII: 33X04XA5AT)
WATER (UNII: 059QF0KO0R)
ALCOHOL (UNII: 3K9958V90M)
GLYCERIN (UNII: PDC6A3C0OX)
HYDROXYETHYL CELLULOSE, UNSPECIFIED (UNII: T4V6TWG28D)
SODIUM HYDROXIDE (UNII: 55X04QC32I)
NIACINAMIDE (UNII: 25X51I8RD4)
WORMWOOD OIL (UNII: 01756N87N8)
SPEARMINT OIL (UNII: C3M81465G5)
ACHILLEA MILLEFOLIUM FLOWER (UNII: YQR8R0SQEA)

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:53634-153-01	15 mL in 1 TUBE; Type 0: Not a Combination Product	11/23/2022	

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	M006	11/23/2022	

Labeler - Malin and Goetz Inc (138615930)