

SALICYLIC ACID- salicylic acid liquid
Rochester Pharmaceuticals

Disclaimer: This drug has not been found by FDA to be safe and effective, and this labeling has not been approved by FDA. For further information about unapproved drugs, [click here](#).

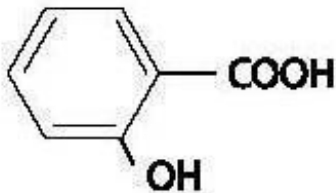
DESCRIPTION

Rx Only

Salicylic Acid, 27.5% Wart Remover

FOR TOPICAL USE ONLY. NOT FOR OPHTHALMIC, ORAL OR INTRA-VAGINAL USE.

Salicylic Acid, 27.5% Wart Remover is a topical preparation containing 27.5% salicylic acid in a film-forming vehicle composed of acrylates copolymer, isopropyl alcohol, isobutyrate, n-butyl acetate, and polyvinyl butyral. The pharmacologic activity of this medication is generally attributed to the keratolytic activity of salicylic acid which is incorporated into a film-forming vehicle designed to cover the wart without the need for a bandage. The chemical structural formula of salicylic acid is:



CLINICAL PHARMACOLOGY

Although the exact mode of action of salicylic acid in the treatment of warts is not known, its activity appears to be associated with its keratolytic action which results in mechanical removal of epidermal cells infected with wart viruses.

INDICATIONS & USAGES

Salicylic Acid, 27.5% Wart Remover is indicated for the topical treatment and removal of common warts and plantar warts.

CONTRAINDICATIONS

Salicylic Acid, 27.5% Wart Remover should not be used by diabetics or patients with impaired blood circulation. Salicylic Acid, 27.5% Wart Remover should not be used on moles, birthmarks, unusual warts with hair growing from them or warts on the face.

PRECAUTIONS

Salicylic Acid, 27.5% Wart Remover is for external use only. Do not permit Salicylic Acid, 27.5% Wart Remover to contact eyes or mucous membranes. If contact with eyes or mucous membranes occurs, immediately flush with water for 15 minutes. Salicylic Acid, 27.5% Wart Remover should not be allowed to contact normal skin surrounding the wart. Treatment should be discontinued if excessive

irritation occurs. Salicylic Acid, 27.5% Wart Remover is flammable and should be kept away from fire or flame. Keep bottle tightly capped when not in use.

KEEP THIS AND ALL MEDICATIONS OUT OF THE REACH OF CHILDREN.

ADVERSE REACTIONS

A localized irritant reaction may occur if Salicylic Acid, 27.5% Wart Remover is applied to the normal skin surrounding the wart. Any irritation may normally be controlled by temporarily discontinuing use and by applying the medication only to the wart site when treatment is resumed.

DOSAGE & ADMINISTRATION

Prior to application of Salicylic Acid, 27.5% Wart Remover, soak wart in warm water for five minutes. Remove any loosened tissue by gently rubbing with a brush, wash cloth, emery board or pumice stone. Dry thoroughly. Using the brush applicator supplied, apply twice to entire wart surface, allowing the first application to dry before applying the second. Treatment should be once or twice a day and should continue as directed by physician. Be careful not to apply to surrounding skin. Clinically visible improvement will normally occur during the first or second week of therapy. Maximum resolution may be expected after four to six weeks of drug use.

HOW SUPPLIED

Salicylic Acid, 27.5% Wart Remover is supplied in 10 mL amber glass bottles with a brush applicator - NDC 49908-237-10

Store at 20°C to 25°C (68°F to 77°F), excursions permitted between 15°C and 30°C (between 59°F and 86°F). Brief exposure to temperatures up to 40°C (104°F) may be tolerated provided the mean kinetic temperature does not exceed 25°C (77°F); however, such exposure should be minimized. Protect from freezing.

Manufactured for: Rochester Pharmaceuticals • Doylestown, PA 18901 • 1-866-458-1772
www.RochesterPharm.com

SA27-PI-0915

INSTRUCTIONS FOR USE

Your health care provider has prescribed Salicylic Acid, 27.5% Wart Remover, a topical prescription preparation for the treatment of common and plantar warts. In order for Salicylic Acid, 27.5% Wart Remover to work correctly and ensure maximum benefit, the following instructions should be followed carefully. Of course, as with any medication, always consult your health care provider if you experience any discomfort or unexpected reactions.

STEP 1: WASH

- Soak wart area in warm water for about 5 minutes.
- Remove any loosened tissue by gently rubbing with a brush, wash cloth, emery board, or pumice stone.
- Dry thoroughly.

STEP 2: BRUSH

- Using the brush applicator supplied, apply twice to entire wart surface, allowing the first application to dry before applying the second.
- Be careful not to apply to surrounding skin.
- Leave Salicylic Acid, 27.5% Wart Remover on wart area after it dries.

Repeat Step 1 and Step 2 once or twice daily as advised by your health care provider. Clinically visible

improvement will normally occur during the first or second week of therapy.

Label and Carton

NDC 49908-237-10

Indications and Usage: See insert for full Prescribing Information.
Store at 20°C to 25°C (68°F to 77°F), excursions permitted between 15°C and 30°C (between 59°F and 86°F). Protect from freezing.
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For topical use only
Not for ophthalmic use

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Wart Remover**
10 mL

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Rochester
PHARMACEUTICALS

09/15

10 mL

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**Salicylic Acid, 27.5%
Wart Remover**

Rochester
PHARMACEUTICALS

10 mL

Ingredients:
Each mL of Salicylic Acid, 27.5% Wart Remover contains salicylic acid, 27.5% in a film-forming vehicle composed of acrylates copolymer, isopropyl alcohol, isobutyrate, n-butyl acetate, and polyvinyl butyral.

KEEP THIS AND ALL MEDICATIONS OUT OF THE REACH OF CHILDREN.

Dosage and Administration:
Use as directed by your physician. See insert for full Prescribing Information.

10 mL

09/15

SALICYLIC ACID

salicylic acid liquid

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:49908-237
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
SALICYLIC ACID (UNII: O414PZ4LPZ) (SALICYLIC ACID - UNII:O414PZ4LPZ)	SALICYLIC ACID	275 mg in 1 mL

Inactive Ingredients

Ingredient Name	Strength
ISOPROPYL ALCOHOL (UNII: ND2M416302)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:49908-237-10	1 in 1 CARTON		
1		10 mL in 1 BOTTLE, WITH APPLICATOR; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
unapproved drug other		11/07/2011	

Labeler - Rochester Pharmaceuticals (134473771)

Revised: 11/2015

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