

SALICYLIC ACID- salicylic acid liquid
Acella Pharmaceuticals, LLC

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.

Salicylic Acid, 27.5%

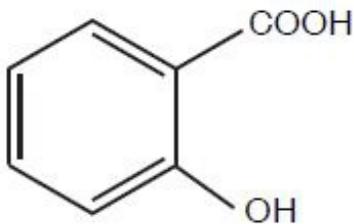
Wart Remover

Rx Only

FOR TOPICAL USE ONLY. NOT FOR OPHTHALMIC, ORAL OR INTRAVAGINAL USE.

DESCRIPTION:

Salicylic Acid, 27.5% Wart Remover is a topical preparation containing 27.5% salicylic acid in a film-forming vehicle composed of isopropyl alcohol, isobutyrate, acrylates copolymer, N butyl acetate and polyvinyl butyrate. The pharmacologic activity of Salicylic Acid, 27.5% Wart Remover 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 structural formula of salicylic acid is:



CLINICAL PHARMACOLOGY:

Although the exact mode of action for 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 AND USES:

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 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 AND 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 or emery board. 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 use.

HOW SUPPLIED:

Salicylic Acid, 27.5% Wart Remover is supplied in 10 mL amber bottles with a brush applicator, (NDC 42192-135-10).

Store at controlled room temperature, 15° - 30° (59° - 86°F).

MANUFACTURED FOR:

Acella Pharmaceuticals, LLC
Alpharetta, GA 30009
1-800-541-4802
Rev. 0611

PATIENT INSTRUCTIONS:

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 to 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 loose tissue using a 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.

MANUFACTURED FOR:

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PRINCIPAL DISPLAY PANEL - 10 mL

NDC 42192-135-10

**Salicylic
Acid, 27.5%
WART REMOVER**

Film-Forming Vehicle

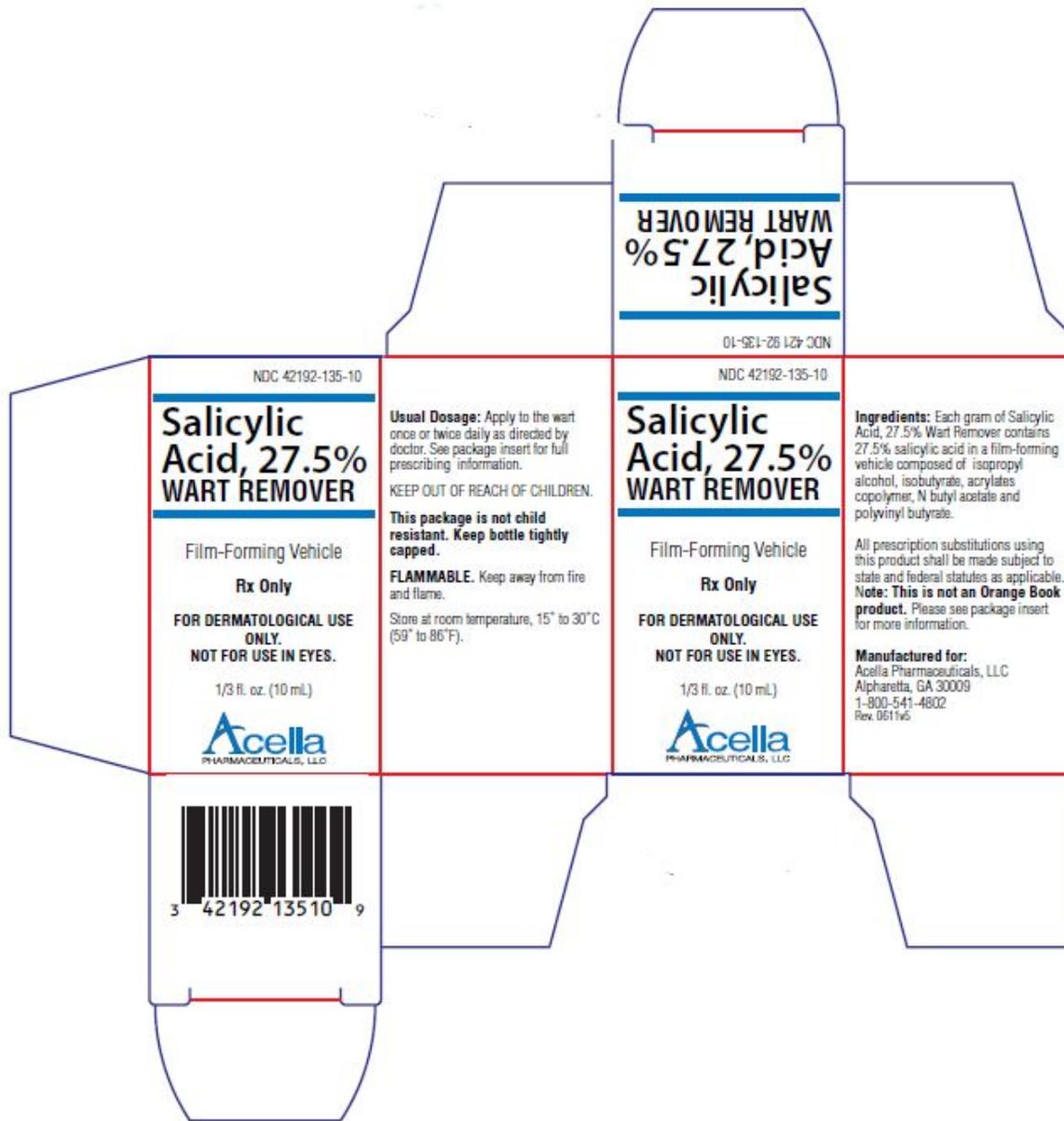
Rx Only

**FOR DERMATOLOGICAL USE
ONLY.**

NOT FOR USE IN EYES.

1/3 fl. oz. (10 mL)

**Acella
PHARMACEUTICALS, LLC.**



SALICYLIC ACID

salicylic acid liquid

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:42192-135
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)	
BUTYL ACETATE (UNII: 464P5N1905)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:42192-135-10	1 in 1 CARTON	10/10/2011	
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		10/10/2011	

Labeler - Acella Pharmaceuticals, LLC (825380939)

Registrant - Acella Pharmaceuticals, LLC (825380939)

Establishment

Name	Address	ID/FEI	Business Operations
Acella Pharmaceuticals, LLC		825380939	manufacture(42192-135)

Revised: 1/2024

Acella Pharmaceuticals, LLC