SALICYLIC ACID- salicylic acid solution
Trinity 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.

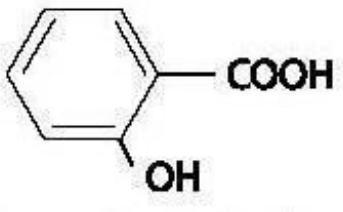
Salicylic Acid, 27.5%

Rx only

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

DESCRIPTION

Salicylic Acid, 27.5% 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 butyrate. 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 for salicylic acid in the treatment of warts is unknown, 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% is indicated for the topical treatment and removal of common warts and plantar warts.

CONTRAINDICATIONS

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

PRECAUTIONS

Salicylic Acid, 27.5% is for external use only. Do not permit Salicylic Acid, 27.5% 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% should not be allowed to contact normal skin surrounding the wart. Treatment should be discontinued if excessive irritation occurs. Salicylic Acid, 27.5% is flammable and should be kept away from fire or flame. Keep bottle tightly capped when not in use.

ADVERSE REACTIONS

A localized irritant reaction may occur if Salicylic Acid, 27.5% 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% 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% is supplied in 10 mL amber glass bottles with brush applicator - NDC 54295-304-11.

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

KEEP THIS AND ALL MEDICATIONS OUT OF REACH OF CHILDREN.

Marketed By:
Trinity Pharmaceuticals LLC
1 International Plaza, Suite 550
Philadelphia, PA 19113
TrinityPharmaLLC.com
REV 11/13

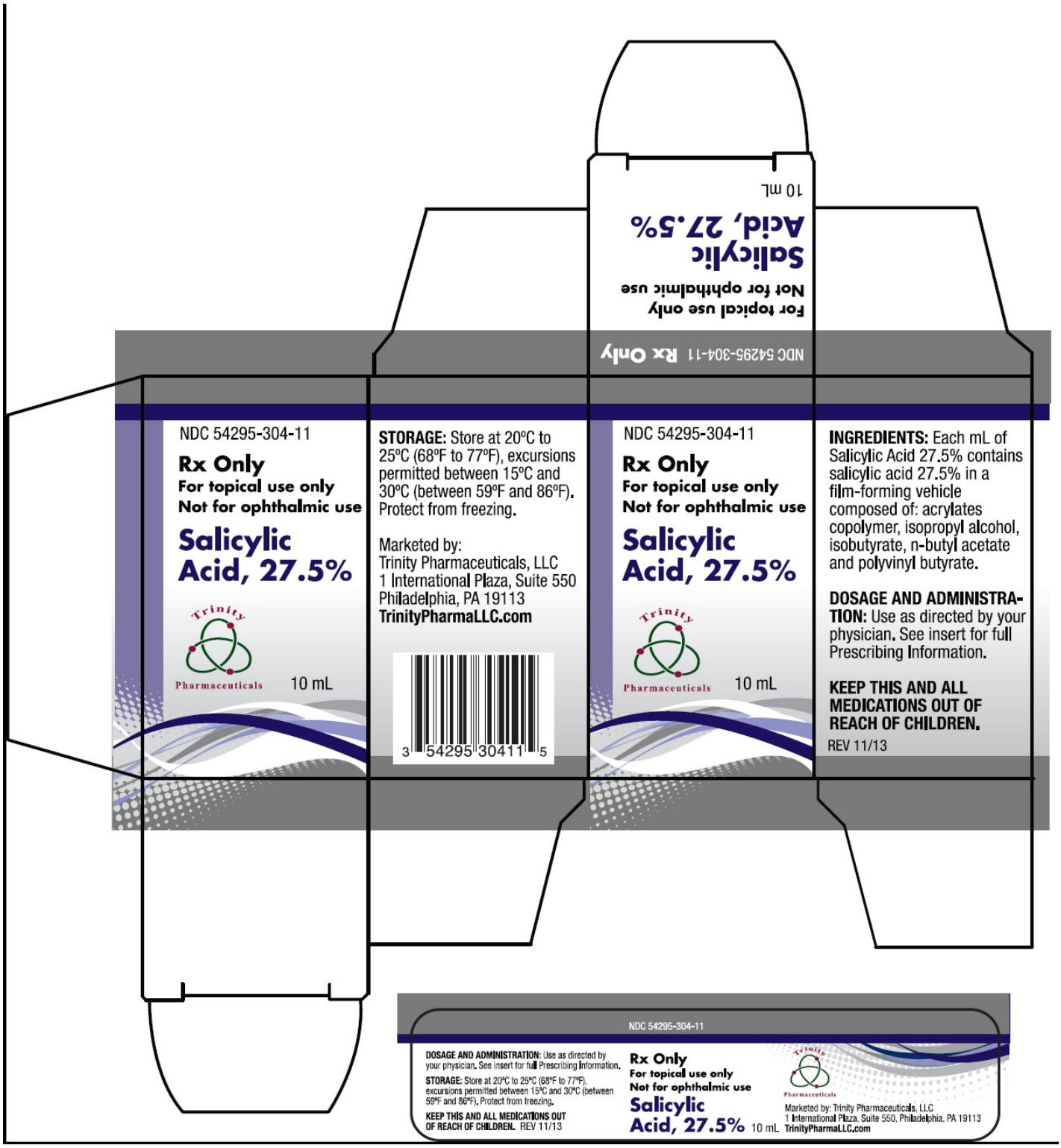
Salicylic Acid, 27.5% 10 mL Container Label Principal Display Panel Text:

NDC 54295-304-11

Rx only

For topical use only
Not for ophthalmic use

Salicylic Acid, 27.5%
10 mL



SALICYLIC ACID

salicylic acid solution

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:54295-304
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:54295-304-11	1 in 1 CARTON	11/16/2013	
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		11/16/2013	

Labeler - Trinity Pharmaceuticals, LLC (078671698)

Revised: 3/2023 Trinity Pharmaceuticals, LLC