

28.5% SALICYLIC ACID- salicylic acid solution

Elorac, Inc.

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](#).

28.5% Salicylic Acid Extended Release Antiviral Film-Forming Solution: Package Insert

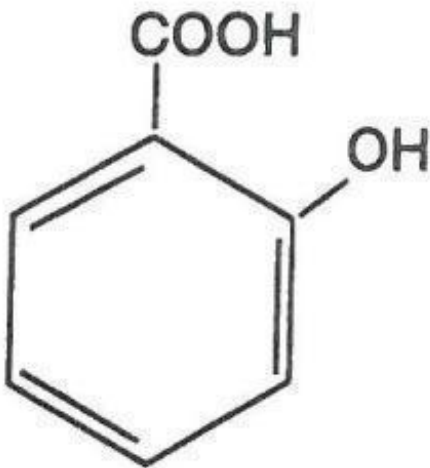
Rx only

FOR TOPICAL USE ONLY.

NOT FOR OPHTHALMIC, ORAL OR INTRAVAGINAL USE.

DESCRIPTION

This Product is a topical preparation containing 28.5% salicylic acid extended release in a proprietary film-forming virucidal solution composed of acrylates copolymer, butyl acetate, carthamus tinctorius seed oil, cocamidopropyl dimethylamine, ethylhexylglycerin, isopropyl alcohol, isopropyl-metacresol, olea europaea fruit oil, phenic acid, phenoxyethanol, polysorbate 80, polyvinyl butyral, trimethyl pentanyl diisobutyrate, and water. The pharmacologic activity of the Product is generally attributed to the keratolytic activity of salicylic acid, which is incorporated into a polyacrylic, film-forming virucidal solution 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 unknown, its activity appears to be associated with its keratolytic action, which results in mechanical removal of epidermal cells infected with wart viruses. This Product incorporates a unique patented extended release form of salicylic acid that provides for enhanced release of salicylic acid for over 24 hours.

The virucidal complex incorporated into this Product's proprietary solution is designed to help reduce risk of reinfection at the wart site, as well as prevent viral contamination of the product under normal usage.

INDICATIONS AND USAGE

This Product is indicated for the topical treatment and removal of common warts and plantar warts.

CONTRAINDICATIONS

Patients with diabetes or impaired blood circulation should not use the Product. This Product also should not be used on moles, birthmarks, and unusual warts with hair growing from them, or warts on the face.

PRECAUTIONS

This Product is for external use only. Do not permit it to contact eyes or mucous membranes. If contact with eyes or mucous membranes occurs, immediately flush with water for 15 minutes. The Product should not be allowed to contact normal skin surrounding the wart site, since localized irritation may occur. Treatment should be discontinued if excessive irritation occurs.

The Product is flammable. Keep away from fire or flame. Keep bottle tightly capped when not in use.

ADVERSE REACTIONS

A localized irritant reaction may occur if this Product 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 applying the Product, soak wart in warm water for five minutes. Remove any loose tissue by gently rubbing with a washcloth, emery board, or pumice stone. Dry the wart site thoroughly. Using the brush applicator supplied, apply it twice to the entire wart surface, allowing the first application to dry before applying the second. Continue treatment once or twice a day as directed by your healthcare provider. Be careful not to apply to surrounding skin.

Clinically visible improvement normally occurs during the first or second week of therapy. Resolution may be expected after four to six weeks of the Product use, though some warts may take longer to remove.

HOW SUPPLIED

This Product is supplied in 10 mL amber bottles with a brush applicator (NDC 42783-324-10).

Store at 15° to 30°C (59° to 86°F).

Manufactured for:

Elorac, Inc.

Vernon Hills, IL 60061

U.S. Patent No. 6,979,440

Additional Patent Pending

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PATIENT INSTRUCTIONS

Your health care provider has prescribed this Product, a topical prescription preparation for the treatment of common warts and plantar warts. In order for it to work properly 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 washcloth, 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 the Product on wart area after it dries.



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

Clinically visible improvement will normally occur during the first or second week of therapy. Resolution may be expected after four to six weeks of the Product use, though some warts may take longer to remove.



Vernon Hills, IL 60061


28.5% Salicylic Acid Extended Release Antiviral Film-Forming Solution: Container Label Principal Display Panel

NDC 42783-324-10

28.5% Salicylic Acid Extended Release Antiviral Film-Forming Solution

1/3 fl. oz. (10 mL)

Rx only

<p>FOR DERMATOLOGICAL USE ONLY. NOT FOR USE IN EYES</p> <p>Rx Only</p> <p>Usual Dosage: Apply to the wart once or twice daily as directed by health care provider.</p> <p>See package insert for full prescribing information.</p>	<p>NDC 42783-324-10</p> <p>28.5% Salicylic Acid Extended Release Antiviral Film-Forming Solution</p> <p>Wart Remover</p> <p>1/3 fl. oz. (10 mL)</p>	<p>Manufactured for: Elorac, Inc. Vernon Hills, IL 60061 U.S. Patent No. 6979440 Additional Patent Pending</p> 
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28.5% Salicylic Acid Extended Release Antiviral Film-Forming Solution: Carton Label Principal Display Panel

NDC 42783-324-10

28.5% Salicylic Acid Extended Release Antiviral Film-Forming Solution

1/3 fl. oz. (10 mL)

Rx only

<p>Ingredients: Salicylic acid extended release in a proprietary film-forming solution composed of acrylates copolymer, butyl acetate, carthamus tinctorius seed oil, cocamidopropyl dimethylamine, ethylhexylglycerin, isopropyl alcohol, isopropyl-metacresol, olea europaea fruit oil, phenic acid, phenoxethanol, polysorbate 80, polyvinyl butyral, trimethyl pentanoyl diisobutyrate, water</p> <p>Usual Dosage: Apply to the wart once or twice daily as directed by health care provider.</p> <p>KO Coating</p>	<p>NDC 42783-324-10</p> <p>28.5% Salicylic Acid Extended Release Antiviral Film-Forming Solution</p> <p>Wart Remover</p> <p>FOR DERMATOLOGICAL USE ONLY. NOT FOR USE IN EYES</p> <p>Rx Only</p> <p>See package insert for full prescribing information.</p> <p>1/3 fl. oz. (10 mL)</p>	<p>KEEP OUT OF REACH OF CHILDREN</p> <p>This package is not child resistant.</p> <p>Keep bottle tightly capped.</p> <p>Flammable. Keep away from fire and flame.</p> <p>Store at room temperature, 59° to 86°F (15° to 30°C).</p> <p>Manufactured for: Elorac, Inc. Vernon Hills, IL 60061 U.S. Patent No. 6979440 Additional Patent Pending</p> <p>210313-03/2018 </p>
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28.5% SALICYLIC ACID
salicylic acid solution

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:42783-324
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
salicylic acid (UNII: O414PZ4LPZ) (salicylic acid - UNII:O414PZ4LPZ)	salicylic acid	285 mg in 1 mL

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:42783-324-10	1 in 1 CARTON	04/30/2018	
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		04/30/2018	

Labeler - Elorac, Inc. (832590009)**Registrant** - Elorac, Inc. (832590009)**Establishment**

Name	Address	ID/FEI	Business Operations
Swiss-American CDMO, LLC		080170933	manufacture(42783-324) , analysis(42783-324) , pack(42783-324) , label(42783-324)

Revised: 4/2018

Elorac, Inc.