VIRASAL- 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.

Virasal (27.5% Salycylic Acid) Antiviral Film-Forming Vehicle - Package Insert Text:

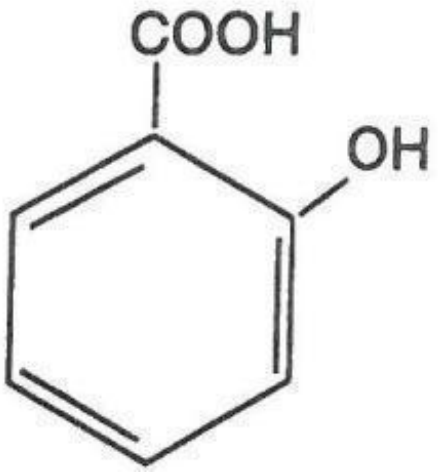
Rx only

FOR TOPICAL USE ONLY.

NOT FOR OPHTHALMIC, ORAL OR INTRAVAGINAL USE.

DESCRIPTION

Virasal is a topical preparation containing 27.5% salicylic acid in a proprietary film-forming vehicle that comprises isopropyl alcohol, butyl acetate, polyvinyl butyral, isopropyl metacresol, trimethyl pentanyl diisobutyrate, phenic acid and acrylates copolymer. The pharmacologic activity of Virasal is generally attributed to the keratolytic activity of salicylic acid which is incorporated into a polyacrylic, film-forming virucidal 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 unknown, its activity appears to be associated with its keratolytic action, which results in mechanical removal of epidermal cells infected with wart viruses.

The virucidal complex incorporated into Virasal's proprietary vehicle 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

Virasal 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 Virasal. Virasal also should not be used on moles, birthmarks, and unusual warts with hair growing from them, or warts on the face.

PRECAUTIONS

Virasal is for external use only. Do not permit Virasal to contact eyes or mucous membranes. If contact with eyes or mucous membranes occurs, immediately flush with water for 15 minutes. Virasal should not be allowed to contact normal skin surrounding wart, since localized irritation may occur. Treatment should be discontinued if excessive irritation occurs. Virasal 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 Virasal 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 Virasal, soak wart in warm water for five minutes. Remove any loosened tissue by gently rubbing with a brush, wash cloth, or emery board. Dry wart site thoroughly. Using the brush applicator supplied, apply Virasal twice to entire wart surface, allowing the first application to dry before applying the second. Continue treatment once or twice a day 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 Virasal use.

HOW SUPPLIED

Virasal is supplied in 10ml amber bottles with a brush applicator (NDC 42783-312-10).

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

Manufactured for:
Elorac, Inc.
Vernon Hills, IL 60061

U.S. Patent Pending

Revised 06/2011

221619

Virasal (27.5% Salycylic Acid) Antiviral Film-Forming Vehicle - Container Label Principal Display Panel Text:

NDC 42783-312-10

Virasal (27.5% Salycylic Acid) Antiviral Film-Forming Vehicle

Wart Remover

FOR TOPICAL USE ONLY
NOT FOR USE IN THE EYES

Rx only

1/3 fl. oz (10 mL)

Virasal (27.5% Salycylic Acid) Antiviral Film-Forming Vehicle - Carton Label Principal Display Panel Text:

NDC 42783-312-10

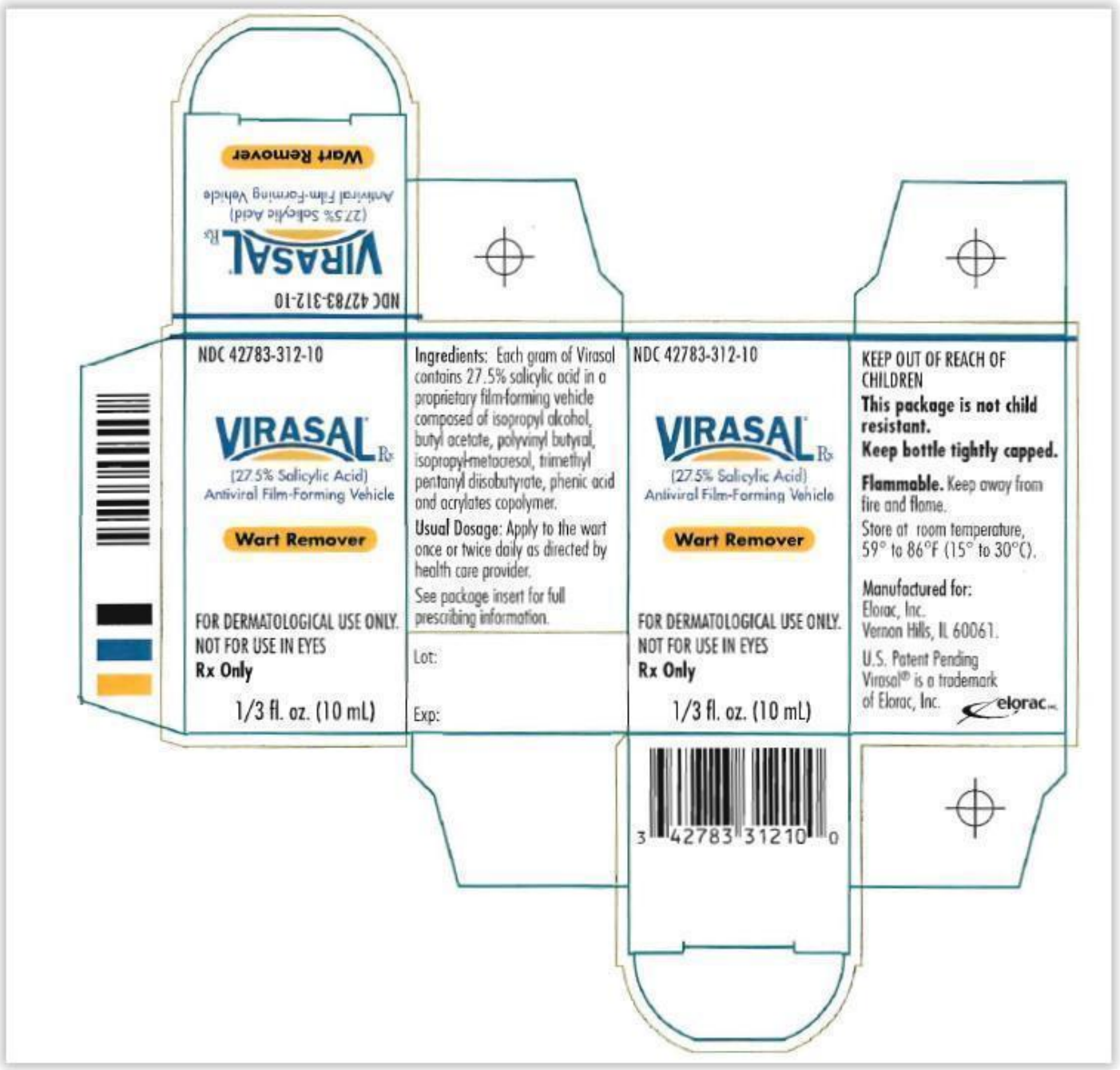
Virasal (27.5% Salycylic Acid) Antiviral Film-Forming Vehicle

Wart Remover

FOR DERMATOLOGICAL USE ONLY
NOT FOR USE IN THE EYES

Rx only

1/3 fl. oz (10 mL)



VIRASAL

salicylic acid solution

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:42783-312
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

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:42783-312-10	1 in 1 CARTON	04/01/2011	
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		04/01/2011	

Labeler - Elorac, Inc. (832590009)

Registrant - Elorac, Inc. (832590009)

Revised: 1/2020 Elorac, Inc.