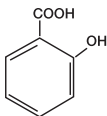


Rx Only

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

Description

Durasal™ is a topical preparation for treatment of common and plantar warts containing 26% salicylic acid in a film-forming vehicle composed of isopropyl alcohol, butyl acetate, polyvinyl butyral, trimethyl pentanyl diisobutyrate and acrylates copolymer. The pharmacologic activity of Durasal 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 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 and uses

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

Contraindications

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

Precautions

Durasal is for external use only. Do not permit Durasal to contact eyes or mucous membranes. If contact with eyes or mucous membranes occurs, immediately flush with water for 15 minutes. Durasal should not be allowed to contact normal skin surrounding wart. Treatment should be discontinued if excessive irritation occurs. Durasal 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 Durasal 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 Durasal, 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 drug use.

How supplied

Durasal is supplied in 10ml amber bottles with a brush applicator (NDC 42783-301-10).

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