after exposure to podofilox at concentrations up to 0.008 µg/mL without metabolic transformation related to potential oncogenicity was observed in BALB/3T3 cells concentrations up to 5 mg/plate, with and without metabolic activation. No cell changes resembling carcinoma after cessation of treatment. In one reported experiment, epidermal carcinoma of the animal studies, in general, have not shown the drug substance, podofilox, to be carcinogetic. Reports of lifetime carcinogenicity studies in mice are not available. Published **Carcinogenesis, Mutagenesis and Impairment of Fertility**

**INDICATIONS AND USAGE**

Condylox 0.5% Solution is indicated for the topical treatment of external genital warts (Condyloma acuminatum). This product is not indicated in the treatment of penile or mucous membrane warts (see **PRECAUTIONS**).

Podofilox has the following structural formula:

$$\text{CH}_3\text{CH}_2\text{OH}$$

Podofilox has a molecular weight of 414.4 daltons, and is soluble in alcohol and sparingly soluble in water. Its chemical name is 5,8,8a,9-Tetrahydro-9-hydroxy-5-methoxy-1,3-oxafuran-6(5aH)-one. Podofilox is sparingly soluble in water. Its chemical name is 5-(3,4,5-trimethoxyphenyl)furo[3',4':6,7]naphtho[2,3,d]-1,3-dioxol-6(5aH)-one.

**DESCRIPTION**

Condylox is the brand name of podofilox, an antimitotic drug which can be chemically synthesized or purified from the plant families Coniferae and Berberidaceae (e.g., species of Juniperus and Podophyllum). Condylox 0.5% Solution is formulated for topical administration. Each milliliter of solution contains 5 mg of podofilox, in a vehicle containing lactic acid and sodium lactate in alcohol 95%, USP.

Condylox is contraindicated for patients who develop hypersensitivity or intolerance to any component of the formulation. Condylox 0.5% Solution is contraindicated for patients who develop hypersensitivity or intolerance to any component of the formulation.

**DIAGNOSIS**

Although genital warts have a characteristic appearance, histopathologic confirmation should be obtained if there is any doubt of the diagnosis. Differentiating warts from squamous cell carcinoma (so-called “Bowenoid papulosis”) is of particular concern. Squamous cell carcinoma may also be associated with human papillomavirus but should not be treated with Condylox 0.5% Solution.

**PRECAUTIONS**

Data are not available on the safe and effective use of this product for treatment of warts occurring in the perianal area or on mucous membranes of the genital area (including the urethra, rectum and vagina). The recommended method of application, frequency of application, and duration of usage should not be exceeded (see **DOSAGE AND ADMINISTRATION**).

**INFORMATION FOR PATIENTS**

The patient should be provided with a Patient Information leaflet when a Condylox prescription is filled.

**Mechanism of Action**

Treatment of genital warts with podofilox results in necrosis of visible wart tissue. The exact mechanism of action is unknown.

**Pharmacokinetics**

In clinical studies with Condylox Solution, the test product and its vehicle were applied in a double-blind fashion to comparable patient groups. Patients were treated four times per week, and reevaluated at a 2-week follow-up examination. Although the number of patients and warts evaluated at each time period varied, the results among investigators were relatively consistent.

The following table represents the responses noted in terms of frequency of response by lesions treated and the overall response by patients. Data are presented for the 2-week follow-up only for those patients evaluated at that time point.

**Dosage**

The following table represents the responses noted in terms of frequency of response by lesions treated and the overall response by patients. Data are presented for the 2-week follow-up only for those patients evaluated at that time point.

**Pharmacokinetics**

Applications of 0.1 to 1.5 mL resulted in peak serum levels of 1 to 17 ng/mL one to two hours after application. The elimination half-life ranged from 1 to 4.5 hours. The drug was not found to accumulate after multiple treatments.

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