Condylox® Gel 0.5% (podofilox gel) (con’ de lox)

Content Updated: August 2014 Rx only 140349

Physician Information

DESCRIPTION

Podofilox is an antimitotic drug which can be chemically synthesized or purified from the bark of several Coniferae and related dicotyledonous trees. Conifer resin has been used as a medicine for thousands of years and is the source of several antitumor compounds. Podofilox is currently purified from Podophyllum hexandrumliterature indicates that the drug contains the seedling of Podophyllum, but the exact mechanism of action is unknown.

Mechanism of Action

Podofilox Gel 0.5% is indicated for the topical treatment of anogenital warts caused by human papillomavirus which should not be treated with Condylox Gel 0.5%. Differentiating warts from squamous cell carcinoma and "Bowenoid papulosis" is essential. See the subsection of the INDICATIONS AND USAGE section. Condylox Gel 0.5% is intended for cutaneous use only. Avoid contact with the eyes. If contact with the eyes occurs, patients should immediately flush the eyes with copious amounts of water and seek medical advice.

Drug Product is Flammable.

GUIDELINES

GENERAL

This product is not available on the sale and effective use of this product for the treatment of warts occurring 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).

INDICATIONS AND USAGE

Condylox Gel 0.5% is contraindicated for patients who develop hypersensitivity or sensitization to podofilox. Sensitivity reactions to podofilox have not been observed in patients treated with Condylox Gel 0.5%.

WARNINGS

Correct diagnosis of the lesions to be treated is essential. See the subsection of the WARNINGS section. Condylox Gel 0.5% is intended for cutaneous use only. Avoid contact with the eyes. If contact with the eyes occurs, patients should immediately flush the eyes with copious amounts of water and seek medical advice.

DOSAGE AND ADMINISTRATION

This medication should be used only as directed by the health care provider. Patients receiving this medication should be aware that the frequency of application, and duration of usage should not be exceeded (see DOSAGE AND ADMINISTRATION).

WHAT IS PODOFILOX?

Podofilox is a member of the podophyllotoxin class of antimitotic agents. It is a water-soluble, colorless, odorless, and odorless compound. Its chemical name is [5R,-(5α,13β,15β)-13-

DOSAGE AND ADMINISTRATION

Treatment of anogenital warts with podofilox results in necrosis of visible wart tissue when treated with Condylox Gel 0.5%. Patients treated with Condylox Gel 0.5% should receive the following information and instructions. This information is intended to aid in the safe and effective use of this product for the treatment of warts occurring on mucous membranes of the genital area (including the urethra, rectum and vagina).

1) This medication should be used only as directed by the health care provider. Patients receiving this medication should be aware that the frequency of application, and duration of usage should not be exceeded (see DOSAGE AND ADMINISTRATION).

2) Patients should be advised not to use this medication for any disorder other than warts occurring 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).

3) Patients should report any signs of adverse reactions to the health care provider.

4) If no improvement is observed after 4 weeks of treatment, discontinues the medication and seek medical advice.

Pharmacokinetics

In systemic absorption studies in 52 patients, topical application of 0.05 mL of podofilox solution at doses up to 25 mg/kg (75 mg/m2), indicate that podofilox should be considered sparingly soluble in water. Its chemical name is [5R,-(5α,13β,15β)-13-

Mechanism of Action

Mechanism of Action

Podofilox Gel 0.5% is formulated for topical administration.
Pregnancy
Pregnancy Category C: 0.5% podofilox solution was not teratogenic in the rabbit following topical application of up to 0.21 mg/kg (2.85 mg/m², approximately 2,000 times the usual human dose) of the drug to the shaved abdomen daily for 5 days during organogenesis. However, teratogenicity was observed in the rat following intraperitoneal administration of 5 mg/kg (29.5 mg/m², approximately 19 times the usual human dose) of podofilox on the 10th day of gestation. It is not known whether podofilox is excreted in human milk. Because of the potential for serious adverse reactions in nursing women from a potentially effective drug, a decision should be made whether to discontinue nursing or to discontinue the drug, taking into account the importance of the drug to the mother.

OVERDOSAGE
Adverse effects following systemic administration of podophyllum resin included: nausea, vomiting, fever, diarrhea, bone marrow depression, and oral ulcers. Following 5 to 10 daily intravenous doses of 0.5 to 1 mg/kg/day, significant hematological toxicity occurred (10). Other toxicities occurred at lower doses. Toxicity reported following systemic administration of podofilox in investigational use for cancer treatment included: nausea, vomiting, tachypnea, respiratory failure, leukocytosis, pancytosis, hematuria, renal failure and fever, diarrhea, peripheral neuropathy, altered mental status, lethargy, coma, seizures. Treatment of topical overdosage should include washing the skin free of the gel and symptomatic and supportive therapy.

REFERENCES


ADVERSE REACTIONS

Condylox Gel 0.5% is supplied as 3.5 g of clear gel in aluminum tubes with an applicator tip. NDC 52544-045-13. Store at 20-25°C (68-77°F). [See USP 24].

HOW SUPPLIED

Condylox Gel 0.5% should be applied to the warts with the applicator tip or finger. Condylox Gel 0.5% should be applied to the warts with the applicator tip or finger. Condylox Gel 0.5% should be applied to the warts with the applicator tip or finger.

DOSAGE AND ADMINISTRATION

Condylox Gel 0.5% should be applied to clean, dry skin surfaces to their normal positions. Patients should be instructed to wash their hands thoroughly before and after each application. Condylox Gel 0.5% should be applied to the warts with the applicator tip or finger. Condylox Gel 0.5% should be applied to the warts with the applicator tip or finger.