

# New Drug Information

FROM THE EDITORS OF THE P A P R

## PRODUCT: Veregen

COMPANY: Doak and Kenwood

PHARMACOLOGIC CLASS: Botanical

ACTIVE INGREDIENTS: Sinecatechins 15%; oint.

**INDICATION:** External genital and perianal warts (*Condylomata acuminata*) in immunocompetent patients  $\geq 18$  yrs of age.

**PHARMACOLOGY:** Veregen is a topical ointment that delivers sinecatechins, a partially purified fraction of the water extract of green tea leaves from *Camellia sinensis* (L.) O Kuntze. Sinecatechins is a mixture of catechins and other components of green tea. Catechins comprise about 85–95% of the drug substance while the other components (gallic acid, theobromine, and caffeine) make up about 2.5%. The remainder of the drug substance contains undefined botanical constituents derived from green tea leaves. The vehicle for Veregen is a water-free mixture that contains isopropyl myristate, white petrolatum, cera alba, propylene glycol palmitostearate, and oleyl alcohol.

The mechanism of action of sinecatechins is unknown. Antioxidant properties have been demonstrated in vitro, but the clinical significance of this finding is unknown.

**CLINICAL TRIALS:** The safety and efficacy of Veregen was evaluated in two randomized, double-blind, vehicle-controlled studies in immunocompetent patients. The median baseline number of warts was 6 (range 2–30). The primary efficacy outcome measure was the response rate, defined as the proportion of patients who had complete clinical (visual) clearance of all warts (both baseline and new ones) by week

16. Subjects applied the ointment three times daily for up to 16 weeks or until complete clearance. Data was examined both for patients in the US only and for those in all countries in which testing occurred. For all countries, treatment with Veregen resulted in a complete clearance rate of 53.6%, compared to 35.3% for vehicle. For patients in the US alone, the response rates were 23.8% for Veregen and 0% for vehicle. When examined for efficacy by gender, 47.3% of males treated with Veregen had complete clearance compared to 60.4% of females, while 28.8% of males using vehicle had a complete clearance, compared to 43.8% of females using vehicle. The median time to clearance was 16 weeks in one study and 10 weeks in the other. In patients with complete clearance, the rates of recurrence of warts 12 weeks after completion of therapy was 6.8% for those who had used Veregen compared with 5.8% for those who had used vehicle.

**ADULTS:**  $\geq 18$  yrs: Wash hands. Apply ointment to each wart 3 times daily for up to 16 weeks. Do not cover treated area.

**CHILDREN:**  $< 18$  yrs: not recommended.

**PRECAUTIONS:** Do not use on internal or mucous membrane warts or on broken skin. Caution with tampon insertion (avoid inadvertent internal application). Wash ointment off if severe reaction occurs. Avoid sexual contact with ointment on skin. Immunosuppressed. May stain fabrics. Avoid sun, UV light on treated area. Pregnancy (Cat.C). Nursing mothers.

**INTERACTIONS:** Concomitant use of condoms or diaphragm: not recom-

mended (ointment may weaken rubber).

**ADVERSE REACTIONS:** Local reactions (eg, erythema, erosion, edema, itching, burning), phimosis, inguinal lymphadenitis, urethral meatal stenosis, dysuria, rash, desquamation, bleeding, hypersensitivity, superinfection.

**HOW SUPPLIED:** Oint–15g, 30g

## Facts about genital warts

- **Genital warts**, also known as *condylomata acuminata* or venereal warts, are a common sexually transmitted infection.

- **Treatments** for genital warts include medications and surgery. The underlying cause of the warts cannot be eradicated, and they are considered to be a sign of a serious health concern. Genital warts are caused by the human papillomavirus (HPV), a primary cause of cervical cancer. HPV is also associated with other types of genital cancers, including cancer of the penis.

- **Medical treatments** for genital warts in addition to Veregen include imiquimod (Aldara), an immune system booster; podofilox (Condylox), which destroys the wart; and trichloroacetic acid, or TCA, which burns off genital warts.

- **Surgical treatments** include cryotherapy, which causes a blister to form around the wart, leading the lesions to slough off; electrocautery, which burns off warts; surgical excision; and laser treatment.

- **Preventing the spread** of genital warts is important. One way is for patients to use a condom during sex to prevent skin-to-skin contact. Another option is the cervical cancer vaccine, which protects against some of the most dangerous strains of HPV.

**Data from** Genital warts. MayoClinic.com. <http://www.mayoclinic.com/health/genital-warts/DS00087/DSECTION=1>. Accessed March 6, 2008.



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