

Sinecatechins (Veregen™)

**Criteria for Use
January 2013**

VHA Pharmacy Benefits Management Services, the Medical Advisory Panel, and VISN Pharmacist Executives

The following recommendations are based on current medical evidence. The content of the document is dynamic and will be revised as new clinical data become available. The purpose of this document is to assist practitioners in clinical decision making, to standardize and improve the quality of patient care, and to promote cost-effective drug prescribing. The clinician, however, must make the ultimate judgment regarding the propriety of any course of treatment in light on individual patient situations

Refer Imiquimod CFU at www.pbm.va.gov or <http://vaww.pbm.va.gov>

EXCLUSION CRITERIA (If one is selected, patient is NOT eligible)
<input type="checkbox"/> Immunocompromised patient <input type="checkbox"/> Treatment of urethral, intra-vaginal, cervical, rectal or intra-anal human papilloma viral disease <input type="checkbox"/> Application to open wounds
INCLUSION CRITERIA
<input type="checkbox"/> Patient is under the care of a dermatologist, gynecologist, urologist, or Women's Health provider and meets one of the following conditions: <u>Extensive or severe external genital or perianal warts (Both must be selected to be eligible):</u> <input type="checkbox"/> Large number (≥ 10) of individual warts or warts involving large areas of skin in areas otherwise difficult to treat with typical destructive modalities such as cryotherapy, podophyllin or trichloroacetic acid. <input type="checkbox"/> Documented inadequate response or intolerance to other patient-administered agents (podofilox for at least 4 one-week cycles and imiquimod for at least 4 one-week cycles). <u>Isolated external genital warts (<10) on penile shaft, glans or vulvar areas or isolated perianal warts (Both must be selected to be eligible):</u> <input type="checkbox"/> Documented inadequate response or intolerance to at least two of these treatment modalities: topical 0.5% podofilox (at least 4 one-week cycles), podophyllin 25% (at least 4 weekly applications), trichloroacetic acid (80% or higher strength for at least 4 weekly applications), and cryotherapy (at least 4 cycles). <input type="checkbox"/> Documented inadequate response or intolerance to imiquimod (at least 4 one-week cycles).
DOSAGE AND ADMINISTRATION (Refer to PI for dosage recommendations in organ dysfunction)
Topical administered three times per day until complete clearance of all warts (maximum of 16 weeks of therapy). Each wart should receive approximately 0.5cm strand of sinecatechins to ensure complete coverage.
RECOMMENDED MONITORING
<ul style="list-style-type: none"> • Tolerability of local adverse effects • Patient adherence to dosage regimen
ISSUES FOR CONSIDERATION
<ul style="list-style-type: none"> • FDA approved indication for use: Sinecatechins 15% ointment is indicated for the topical treatment of external genital and perianal warts (<i>Condylomata acuminata</i>) due to human papillomavirus infection (HPV) in immunocompetent patients 18 years and older.