

green tea leaf extract (VEREGEN°)

An aggressive topical treatment for anogenital warts

Abstract

- Anogenital warts are epithelial proliferations caused by a sexually transmitted virus. In immunocompetent patients, this is a mild, more or less troublesome, condition.
- One option for clearing the lesions are self-applied topical products containing *imiquimod* or *podophyllotoxin*.
- A 10% ointment of a dry extract obtained from the leaves of a variety of green tea has been granted marketing authorisation in this situation in a number of European countries (Veregen°, Expanscience).
- Clinical evaluation includes no trials versus *imiquimod* or *podophyllotoxin*, but was based on two trials versus a coloured ointment containing excipients

but no green tea extract, the precise composition of which was not specified. These double-blind randomised trials included a total of 1005 immunocompetent patients, treated for a maximum of 16 weeks. Thrice daily application of 10% green tea extract ointment led to complete clearance of anogenital warts in 52% of patients versus 35% in the control groups (statistically significant difference).

- The known adverse effects mainly consist of frequent, sometimes severe, local reactions: erythema, pruritus, ulceration, etc. Phimosis can occur when treating warts on the foreskin.
- Some animal data suggest that women who are, may be or could become pregnant should avoid using green tea extract ointment.
- Green tea extract ointment weakens condoms and diaphragms.

- Green tea extract ointment is brown and stains clothing and bedding. It is applied more frequently than topical *imiquimod* or *podophyllotoxin*.
- In practice, ointment containing green tea leaf extract has not been shown to offer any advantages over existing treatments for patients with anogenital warts.

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NOTHING NEW



In patients with troublesome anogenital warts, who are able and willing to apply a topical treatment themselves, ointment containing green tea leaf extract has no demonstrated advantages in terms of efficacy, adverse effects or convenience over topical treatments containing *imiquimod* or *podophyllotoxin*. In practice, it is better to choose the better established drugs *imiquimod* or *podophyllotoxin*.

Rev Prescrire 2015; 35 (375): 6.

ASSESSMENT ELSEWHERE

Green tea leaf extract

Arznei-Telegramm (Germany): "Serious local, especially vulvar, reactions are very common with ointment containing green tea leaf extract. It has not been compared with other treatments in clinical trials. Given its insufficient evaluation, the high rate of spontaneous clearance and its considerable adverse effects, we advise against the use of ointment containing green tea extract" (1).

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1- "Grüntee-extrakt (Veregen) gegen Feigwarzen (condylomata acuminata)" *Arznei-Telegramm* 2010; 41 (6): 62-63.



In response to our request for information, Expanscience provided us with no documentation on its product.

dry extract of green tea leaves ointment

VEREGEN°

- **100 mg** of refined dry extract of green tea leaves, variety *Camellia sinensis* (L.) O. Kuntze, corresponding to 55 mg to 72 mg of *epigallocatechin gallate* per gram of ointment

topical treatment for anogenital warts

■ **Indication:** "... external genital and perianal warts (*condylomata acuminata*) in immunocompetent patients aged 18 years and older".

[French marketing authorisation, European mutual recognition procedure, following German approval]

Full review (5 pages, 10 references) available in French on request *Rev Prescrire* 2015; 35 (375): 6.