
APPROVED PATIENT INFORMATION LEAFLET**SCHEDULING STATUS****S3****VEREGEN™ Ointment****Sinecatechins**

Read all of this leaflet carefully because it contains important information for you

- Keep this leaflet. You may need to read it again.
- Do not share **VEREGEN** with any other person.
- Ask your healthcare provider or pharmacist if you need more information or advice.
- You must see a doctor if your symptoms worsen or do not improve after 4 – 6 weeks.

What is in this leaflet

1. What **VEREGEN** is and what it is used for
2. What you need to know before you take **VEREGEN**
3. How to take **VEREGEN**
4. Possible side effects
5. How to store **VEREGEN**
6. Contents of the pack and other information

1. What VEREGEN is and what it is used for

VEREGEN™ is a herbal medicinal product for skin use only. Its active substance is an extract from green tea leaves (sinecatechins). **VEREGEN™** is used to locally treat warts (*Condylomata acuminata*) on the surface of the genitals (sexual organs) and around the anus. **VEREGEN™** is used in adults with normal function of their immune system.

2. What you need to know before you take VEREGEN™

Do not take VEREGEN™:

- if you are hypersensitive (allergic) to green tea extract or any of the other ingredients of **VEREGEN™** (see section 6).

Tell your doctor and do not take **VEREGEN™** if any of these apply to you.

Warnings and precautions

- Talk to your doctor or pharmacist before taking **VEREGEN™** if have any problems with your liver or immune system. **VEREGEN™** should not be used if your liver function is impaired (e.g. abnormal accumulation of fluid in the abdomen, yellow skin due to liver dysfunction) or when your immune system is compromised (either due to illness or due to other medicines you are taking).
- Do not use **VEREGEN™** until the area to be treated has completely healed after previous drug or surgical treatment.
- Avoid contact with the eyes, nostrils, lips and mouth. If the ointment gets on any of these areas inadvertently, it should be wiped off and/or rinsed off with water.
- Do not apply to open wounds, broken or inflamed skin.
- **VEREGEN™** must not be applied on mucous membranes, so it is not a treatment for warts in the vagina, cervix, urethra or inside the anus.
- Female patients with genital warts in the vulvar region should use the ointment with caution as treatment in this area can cause severe local adverse reactions more often.
- Uncircumcised male patients treating warts under the foreskin should retract the foreskin and clean the area daily to prevent phimosis (when the foreskin cannot be pulled back over the head of the penis). When early signs of stricture

occur (e.g. open sores, hardening of the skin or increasing difficulty in retracting the foreskin), you should stop the treatment and consult your doctor.

- **VEREGEN™** does not eliminate the HPV-virus or prevent transmission of the disease, therefore special care should be taken before sexual activity; (see section 3. How to use **VEREGEN™** of this leaflet).
- In case your sexual partner is infected with genital warts his/her treatment is advisable and will help to prevent reinfection. You can ask your doctor for advice.
- Do not expose the treated area to sunlight and do not use sunlamps and tanning beds.
- **VEREGEN™** stains clothing and bedding.
- Mild local skin reactions such as redness, itching, irritation (mostly burning), pain and swelling at the site of application are very common and should not lead to discontinuation. They should decrease after the first weeks of treatment; see section '4. Possible side effects'.

Children and adolescents

Do not give **VEREGEN™** to children or adolescents under the age of 18 years.

Other medicines and VEREGEN™

Always tell your health care provider if you are taking any other medicine. (This includes all complementary or traditional medicines.)

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicine or if you have recently had other treatments for warts around the sexual organs or the anus. **VEREGEN™** should not be used together with other treatment at the wart area.

VEREGEN™ should not be used until your skin has healed from other treatments.

VEREGEN™ with food and drink

There is no interaction with food and drink.

As a precaution to avoid interactions / side effects, **VEREGEN™** should not be used with food supplements containing high amounts of extract from green tea leaves.

Pregnancy and breastfeeding

If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist or other health care provider for advice before taking this medicine.

VEREGEN™ is not recommended during pregnancy and breastfeeding.

Driving and using machines

No studies on the effect on the ability to drive and use machines have been performed. However it is unlikely that **VEREGEN™** will have an effect on the ability to drive or use machines.

VEREGEN™ contains isopropyl myristate and propylene glycol monopalmitostearate

VEREGEN™ contains, among other ingredients, high amounts of isopropylmyristate (IPM), which can cause irritation and sensitization of the skin, and propylene glycol monopalmitostearate which may cause skin irritations.

3. How to use VEREGEN™

Do not share medicines prescribed for you with any other person.

Always use this medicine exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure.

The usual dose is up to 0.5 cm of ointment strand (corresponding to 250 mg) for all warts together, applied three times daily (in the morning, at mid-day and in the evening).

Wash hands before and after applying the ointment.

Apply a small amount of **VEREGEN™** to each wart using the fingers, dabbing it on to ensure complete coverage and leaving a thin layer of the ointment on the warts.

Do not apply the ointment internally (into the anus, urethra or into the vagina).

Do not cover the treated area with bandages after you have applied the ointment.

It is not necessary to wash off the ointment from the treated area prior to the next application.

When you wash the treatment area or bathe, apply the ointment afterwards.

Apply **VEREGEN™** three times per day (in the morning, at mid-day and in the evening).

New warts may develop during treatment, which need to be treated in the same way.

Genital warts are a sexually transmitted disease; therefore you may infect your partner by sexual activity. Condoms should be used until complete clearance of all warts. The use of condoms prevents reinfection as well.

VEREGEN™ may weaken condoms and vaginal diaphragms. Before sexual activity, wash off the ointment carefully with warm water and mild soap and apply a condom thereafter. Ask your doctor for additional methods of contraception.

Female patients during menstruation using tampons: insert the tampon before applying the ointment. If you need to change your tampon while the ointment is on your skin, avoid getting the ointment into the vagina. In case of accidental application immediately wash-off the ointment with warm water and mild soap.

Duration of treatment with **VEREGEN™** should be continued until complete clearance of all warts, however no longer than 16 weeks, even if new warts develop during the treatment period. If the warts do not go away or if they come back after treatment please consult your doctor.

Older people

There is limited experience for the use of **VEREGEN™** in older people.

Hepatic impairment

You should not use **VEREGEN™** if your liver function is impaired (e.g. abnormal accumulation of fluid in the abdomen, yellow skin due to liver problems).

If you use more VEREGEN™ than you should

In the event of overdosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison centre.

You may experience more intense local reactions (see sections 2. What you need to know before you use **VEREGEN™** and 4. Possible side effects').

Wash off the extra ointment with mild soap and water.

If you have accidentally swallowed the ointment you should contact your doctor.

If you forget to take VEREGEN™

Continue with the next dose when it is due. Do not take a double dose to make up for forgotten individual doses.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

4. Possible side effects

VEREGEN™ can have side effects.

Not all side effects reported for **VEREGEN™** are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking **VEREGEN™**, please consult your health care provider for advice.

Most of the side effects of **VEREGEN™** are due to its local action on the skin and occur on or around the treated wart area. Many patients experience redness, itching, irritation, pain or swelling. Mild reactions are expected and should ease after the first weeks of treatment. If however, the intensity of local skin reactions is affecting your daily activities or if blisters occur, please consult your doctor. It may be necessary to interrupt treatment. Treatment can be resumed after the skin reaction has subsided. In case of vesicular local reactions please consult your doctor.

If you experience severe local reaction causing unacceptable discomfort e.g. local inflammation/infection, open sore, swelling of lymph nodes or any other serious reaction (e.g. constriction of foreskin or urethra, difficulty passing urine or severe pain) you should stop treatment, wash off the ointment with warm water and mild soap and consult your doctor straight away.

For the assessment of the side effects the following frequency rating was used:

Tell your doctor if you notice any of the following:

Very common side effects

May affect more than 1 in 10 people

- Local skin reactions at the wart site where you have applied **VEREGEN™** including: redness, itching, irritation/burning, pain, swelling, open sores, hardening of the skin, and blisters.

Common side effects

May affect up to 1 in 10 people

- Local skin reactions like flakiness, discharge, bleeding, swelling
- Swelling of lymph nodes (in the groin)
- Constriction of the foreskin of the penis

Uncommon side effects

May affect up to 1 in 100 people

- Local scarring, fissure, skin dryness, discomfort, erosion, increase or loss of sensation, nodule, papules, inflammation of the skin, and changes in skin colour at the application site, local necrosis, eczema
- Pustules at the application site, infections at the application site, genital herpes infection, staphylococcal infection, fungal infection of the vagina, inflammation of the urethra or of the vulva and vagina
- Pain, high frequency or urgency in urinating
- Inflammation of the foreskin and head of the penis, painful sexual intercourse
- Rash, hypersensitivity

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

Reporting of side effects

If you get side effects, talk to your doctor or pharmacist. You can also report side effects to SAHPRA via the “6.04 Adverse Drug Reaction Reporting Form”, found online under SAHPRA’s publications:

<https://www.sahpra.org.za/Publications/Index/8>. By reporting side effects, you can help provide more information on the safety of VEREGEN™.

5. How to store VEREGEN

Store all medicines out of reach of children.

- Store at or below 25 °C.
- Keep the cap tightly closed to protect from moisture.
- Use within 6 weeks of opening the tube.
- Do not use this medicine after the expiry date which is stated on the packaging

after EXP. The expiry date refers to the last day of that month.

- Do not store in a bathroom.
- Return all unused medicine to your pharmacist.
- Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

6. Contents of the pack and other information

What VEREGEN™ contains

- The active substance is an extract from green tea leaves (sin catechins). 1 g of the ointment contains 100 mg of extract (as dry extract, refined) from *Camellia sinensis* (L.) O. Kuntze, folium (green tea leaf) (24-56:1), corresponding to: 55-72 mg of (-)-epigallocatechingallate.
First extraction solvent: water
- The other ingredients are: white soft paraffin (contains all-rac- α -tocopherol), white beeswax, isopropyl myristate, oleyl alcohol, propylene glycol monopalmitostearate

What VEREGEN™ looks like and contents of the pack

- **VEREGEN™** is a brown, smooth ointment, free from gritty particles, presented in 2 tube sizes: 15 g and 30 g.
Not all pack sizes may be marketed.

Holder of Certificate of Registration

Acino Pharma (Pty) Ltd

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Access to the corresponding Professional Information

To be confirmed.