

17.2 FDA-Approved Patient Labeling

PATIENT INFORMATION

Veregen® (sinecatechins) **Ointment, 15%** **Rx Only**

Read this leaflet carefully before you start using Veregen® Ointment, 15% and each time you refill your prescription. There may be new information. This information does not take the place of your doctor's advice. If you have any questions about Veregen® Ointment, 15% or your condition ask your doctor or pharmacist. Only your doctor can prescribe Veregen® and determine if it is right for you.

What is Veregen® Ointment, 15%?

Veregen® Ointment, 15% is a medicine for skin use only (topical) for the treatment of warts on the outside of the genitals and around the outside of the anus. It is not a treatment for warts in the vagina, cervix, or inside the anus. Your doctor may recommend examination and screening tests (such as a Pap smear) to evaluate these areas.

Who should not use Veregen® Ointment, 15%?

Do not use Veregen® Ointment, 15% if you are **allergic** to an ingredient in Veregen® Ointment, 15%. **The list of ingredients is at the end of this leaflet.**

What should I tell my doctor before using Veregen® Ointment, 15%?

Tell your doctor about all your health conditions and all the medicines you take including prescription, over-the-counter medicine, vitamins, supplements, and herbals. Be sure to tell your doctor if you are:

- **pregnant or planning to become pregnant**, as it is not known if Veregen® Ointment, 15% can harm your unborn baby. Your doctor will determine whether the benefit outweighs the risk.
- **breastfeeding**, as it is not known if Veregen® Ointment, 15% can pass into your milk and if it can harm your baby.
- **using any other type of skin product or have open wounds on the area to be treated.** Veregen® Ointment, 15% should not be used until your skin has healed from other treatments applied to the same area.
- **immunocompromised.** This means that your immune system cannot fight infections as well as it should.

How should I use Veregen® Ointment, 15%?

- Use Veregen® Ointment, 15% only on the area affected **exactly** as prescribed by your doctor.
- **Wash your hands before and after application of Veregen® Ointment, 15%.** A small amount of the ointment should be applied to all warts using your finger(s), dabbing it on to ensure complete coverage and leaving a thin layer of the ointment on the warts as directed by your doctor.
- **Apply Veregen® Ointment, 15% three times per day—in the morning, at noontime and in the evening.**
- Do not wash off the ointment from the treated area before the next application. When you wash the treatment area or bathe, apply the ointment afterwards.
- Treatment with Veregen® Ointment, 15% should be continued until complete clearance of all warts, however **no longer than 16 weeks.** If your warts do not go away, or if they come back after treatment call your doctor.
- Veregen® Ointment, 15% is not a cure for warts on your genitals or around your anus with certainty. New warts may develop during or after treatment, and may need treatment.

What should I avoid while using Veregen® Ointment, 15%?

- Do not apply Veregen® Ointment, 15% on open wounds or into the vagina or into the anus.
- Genital warts are a sexually transmitted disease, and you may infect your partner.
- Avoid sexual contact (genital, anal or oral) when Veregen® Ointment, 15% is on your genital or perianal skin. If you do choose to have sexual contact, you must wash off the ointment carefully before having protected sexual contact as the ointment may weaken condoms and vaginal diaphragms. Talk to your doctor about safe sex practices.
- Avoid contact with your eyes, nostrils and mouth while ointment is on your finger(s).
- Women 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.
- Uncircumcised men treating warts under the foreskin should retract the foreskin and clean the area daily.
- Do not expose the genital area treated with Veregen® Ointment, 15% to sunlight, sunlamps or tanning beds.
- Do not cover the treated area. Loose-fitting undergarments can be worn after applying Veregen® Ointment, 15%.
- Veregen® Ointment, 15% may stain your light colored clothes and bedding. It is recommended to wear darker colored undergarments while using Veregen® Ointment, 15%.

What are the possible side effects of Veregen® Ointment, 15%?

The most common side effects with Veregen® Ointment, 15% are local skin and application site reactions including:

- redness
- swelling
- sores or blisters
- burning
- itching
- pain

Many patients experience itching, reddening or swelling on or around the application site during the course of treatment. Some of these side effects could be a sign of an allergic reaction. If you experience open sores or other severe reactions at the locations you applied Veregen® Ointment, 15%, stop treatment and call your doctor right away.

You may experience other side effects of Veregen® Ointment, 15%, which are not mentioned here. Ask your doctor or pharmacist for more information.

Patients should be aware that new warts may develop during treatment as Veregen® Ointment, 15% is not a cure.

How should I store Veregen® Ointment, 15%?

- Store Veregen® Ointment, 15% refrigerated or up to 77°F (25°C).
- Do not freeze.
- Make sure the cap on the tube is tightly closed.
- Safely throw away Veregen® Ointment, 15% tubes that are out of date or are empty.

Keep Veregen® Ointment, 15% and all medicines out of the reach of children.

General advice about prescription medicines

Medicines are sometimes prescribed for conditions that are not mentioned in patient information leaflets. Do not use Veregen® Ointment, 15% for a condition for which it was not prescribed. Do not give Veregen® Ointment, 15% to other people, even if they have the same symptoms you have. It may harm them. Do not use Veregen® Ointment, 15% after the expiration date on the tube.

This leaflet summarizes the most important information about Veregen® Ointment, 15%. If you would like more information, talk with your doctor. You can ask your pharmacist or doctor for information about Veregen® Ointment, 15% that is written for the doctor.

What are the ingredients in Veregen® Ointment, 15%?

Active ingredient:

A defined green tea extract named sinecatechins.

Inactive ingredients:

Isopropyl myristate, white petrolatum, cera alba (white wax), propylene glycol palmitostearate, and oleyl alcohol.

Veregen® is a registered trademark of MediGene AG, D-82152 Planegg/Martinsried, Germany.

Manufactured by:
C.P.M. Contract Pharma GmbH & Co. KG
Frühlingstrasse 7
D-83620 Feldkirchen-Westerham
Germany

Manufactured for:


PharmaDerm®
A division of Fougera Pharmaceuticals Inc.
Melville, NY 11747 USA

U.S. Patent Nos. 5795911 and 5968973

89NVEXXXXX