PATIENT INFORMATION LEAFLET

VERRUMAL

Solution for application to the skin

Active substances: fluorouracil, salicylic acid

Read all of this leaflet carefully before you start using this medicine because it contains important information for you.
- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What Verrumal is and what it is used for

Verrumal is a wart therapy agent.

Verrumal is used for common warts, for warts on the sole of the foot (plantar warts), as well as for flat warts (plane juvenile warts) on the arms and legs.

2. What you need to know before you use Verrumal

Do not use Verrumal
- if you are allergic to fluorouracil, salicylic acid or any of the other ingredients of this medicine (listed in section 6),
- when you breast-feed,
- if you are pregnant or if you cannot exclude pregnancy with certainty,
- for infants,
- if you're known to have renal dysfunction,
- if you are using certain anti-viral medicines, e.g. to treat chickenpox or shingles (herpes-zoster therapy). You must not use Verrumal if you have received a therapy with Brivudin, Sorivudin and/or similar substance groups as part of a herpes-zoster therapy now or in the last 4 weeks. The active ingredient Fluorouracil together with Brivudine, Sorivudine and their derivatives may significantly increase the side effects of Verrumal. At the earliest 4 weeks after completion of herpes-zoster therapy with brivudine or sorivudine, you can start treatment with fluorouracil. If you are being treated for a herpes-zoster infection or have recently been treated, please inform your doctor about the medicines you are taking.

Verrumal is not intended for use on large areas of skin (over 25 cm^2) and must not be brought into contact with the eyes or mucous membranes.

Warnings and precautions

Please talk to your doctor or pharmacist before using Verrumal
- if you know that you do not have any activity of the enzyme dihydropyrimidine dehydrogenase (DPD) (complete DPD deficiency). This enzyme plays an important role in the degradation of fluorouracil, the active ingredient of Verrumal. Inhibition or reduced activity of this enzyme (e.g. by taking DPD inhibitors such as brivudine or sorivudine) can lead to an accumulation of the active substance fluorouracil. It is therefore important that you do not apply more Verrumal than indicated in section 3 of this package leaflet.

Be careful when using Verrumal if you are taking Phenytoin for epileptic seizures. Concomitant use of Verrumal with Phenytoin may lead to elevated blood levels of Phenytoin. Therefore, you should be examined regularly on an increased Phenytoin blood-level.

If areas with thin epidermis are affected by warts, apply Verrumal less frequently and have the treated area checked by a doctor more frequently as scarring may occur.

Note that regular medical check-ups are required if your ability to feel touch, pain and temperature is limited (sensitivity disorder, e.g., diabetes mellitus).

Verrumal must not come into contact with textiles or acrylic (e.g., acrylic bathtubs) during application. The solution may cause non-removable stains.

Verrumal should not be used on bleeding lesions.

Children

Verrumal must not be used on infants, since the risk of overdose is greater in children than in adults, the recommended treatment area and frequency must not be exceeded, especially in small children.

Other medicines and Verrumal

Tell your doctor or pharmacist if you are taking or using or have recently taken or used or might take or use any other medicines. This is particularly important, because if several medicines are taken at the same time, the effect of individual medicines can be intensified or weakened.

You are not allowed to use Verrumal if you are taking or have taken certain medicines to treat viral diseases such as chickenpox or shingles (brivudine, sorivudine or their derivates) in the last 4 weeks.

You must be particularly careful if you are taking epileptic seizure medicines (phenytoin). Systemic use of fluorouracil in cancer therapy has shown that concomitant use of phenytoin can lead to elevated phenytoin levels.

Due to the possible uptake of salicylic acid, interactions with methotrexate (drugs for the treatment of certain rheumatic diseases, cancer or severe psoriasis) and sulfonylureas (contained in some antidiabetic drugs) are possible.

Pregnancy and breast-feeding

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before using this medicine.

Verrumal must not be used while breast-feeding, during pregnancy and if the possibility of a pregnancy cannot be excluded with certainty.

Driving and using machines

No special precautions are required.

Verrumal contains Dimethylsulfoxid and alcohol (ethanol)

Dimethyl sulfoxide can cause skin irritation.

This medicine contains 160 mg of alcohol (ethanol) in each gram. It may cause burning sensation on damaged skin.

Please note that Verrumal is flammable before the formation of the lacquer film! Do not light a cigarette or stay near open flames until the film is completely dry.

3. How to use Verrumal

Always use Verrumal exactly as your doctor has told you. You should consult with your doctor or pharmacist if you are not sure.

Dosage

Unless otherwise prescribed, Verrumal solution is applied two to three times daily to each wart.

Method of administration

For application to the skin.

Verrumal must be applied only to the wart and should not come in contact with the healthy skin around the wart. If necessary, the surrounding skin should be covered with paste or ointment. Your doctor or pharmacist can recommend an appropriate product if needed.

Open the bottle by pressing the lid down and turning it counterclockwise at the same time. It is recommended to wipe the brush from the neck of the bottle before dabbing. For very small warts, you should use a toothpick or a similar object instead of the brush for more precise application. Before each new application of Verrumal you should remove the existing film coating by simply peeling it off.

If you have warts around or under the nail, make sure that the nail is undamaged and Verrumal cannot get into the nail bed. Verrumal is not intended for use on large areas of skin. The total area treated at the same time should not exceed 25 cm^2.

It is recommended to consult your doctor regularly during the treatment. Based on past experience, it can be of advantage in many cases (e.g. with strongly protruding warts or foot sole warts), if a doctor removes dead tissue during treatment with Verrumal.

Duration of treatment

The average duration of treatment is 6 weeks. After a successful treatment, the therapy should be continued for about a week.

If you have the impression that the effect of Verrumal is too strong or too weak, talk to your doctor or pharmacist.

If you use more Verrumal than you should

In this case, please contact your treating doctor.

If you forget to use Verrumal

Do not use a double dose if you have forgotten the previous application. Continue the treatment as your doctor has told you or as described in this leaflet.

If you stop using Verrumal

In this case, please contact your treating doctor.
If you have any further questions on the use of this product, ask your doctor or pharmacist.

4. Possible side effects

Like all medicines, Verrumal can cause side effects, although not everybody gets them.
- **Very commonly** (more than 1 out of 10 persons treated) redness, inflammation, irritation, burning, pain and itching can occur on the skin of the application site.
- **Commonly** (1 to 10 out of 100 persons treated) bleeding, encrustation and oozing can occur on the skin of the application site. The skin may flake off and erosive skin reactions (loss of the upper skin tissue) may occur. Headaches can occur.
- **Uncommonly** (1 to 10 out of 1,000 persons treated) skin inflammations, oedemas and ulcers can occur at the application site. The eye may suffer from increased lacrimation, itching and dehydration.
- **Rarely** (1 to 10 out of 10,000 persons treated) a strong burning may result in interruption of the therapy.
- Verrumal contains salicylic acid. This ingredient can cause mild irritation such as inflammation of the skin (dermatitis) and hypersensitivity reactions (allergic contact reactions) may occur. These irritations may be manifested by itching, reddening, small blisters that can extend beyond the area of application.
- There can be a whitish discoloration and ablation of the skin in the area around the wart.

Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet.

5. How to store Verrumal

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the label and the carton after "EXP".

Store at room temperature (15-25°C).

After opening, the preparation can be stored for 6 months.

After use, tightly close the bottle, because the preparation will otherwise dry out and can no longer be used as intended. Once Verrumal dries out, it must not be used. Do not use Verrumal when you notice crystals have formed.

Do not throw away any medicines via wastewater. Ask your pharmacist how to throw away medicines you no longer use. These measures will help to protect the environment.

Caution fire hazard: Keep away from open fire and flames.

6. Contents of the pack and other information

What Verrumal contains:

The active substances are fluorouracil and salicylic acid. 100 g of solution for use on the skin contains 0.5 g fluorouracil and 10.0 g salicylic acid.

The other ingredients are: dimethylsulfoxide, ethanol, ethyl acetate, pyroxylin, methacrylic acid methyl ester/methacrylic acid butyl ester copolymer (80:20).

What Verrumal looks like and contents of the pack

Verrumal is a clear, colourless to slightly yellow-orange solution for use on the skin.

Bottle containing 13 ml

Marketing Authorisation Holder and Manufacturer

Almirall Hermal GmbH
Scholtzstraße 3, 21465 Reinbek
tel.: +49 (040) 727 04 0
fax: +49 (040) 727 04 329
e-mail: info@almirall.de
www.almirall.de

This leaflet was last revised in July 2020