Patient leaflet in accordance with the Pharmacists' Regulations (Preparations) - 1986
This medicine is dispensed with a doctor's prescription only

VERRUMAL SOLUTION

Solution for topical application

Active ingredients:
Each 100 gr contain:
Fluorouracil 0.5 gr
Salicylic acid 10 gr

For the list of inactive ingredients and allergens in the medicinal product, see section 6.

Read the entire leaflet carefully before you start using this medicine. This leaflet contains concise information about this medicine.
If you have any further questions, consult with your doctor or pharmacist.

It is recommended to read this leaflet with another family member.

This medicine has been prescribed for you. Do not pass it on to others. It may harm them, even if it seems to you that their medical condition is similar to yours.

1. What is this medicine intended for?

For the treatment of common warts (warts beneath the soles of the feet in areas where pressure is applied to the soles of the feet) and flat warts on hands and feet.

Therapeutic group: anti-wart and keratolytic agents.

2. Before using this medicine

Do not use this medicine:

- if you are sensitive/allergic to the active ingredients, fluorouracil or salicylic acid (salicylates), or to any of the other ingredients of this medicine that are listed in section 6.
- if you are breastfeeding.
- if you are pregnant or if there is a concern that you may be pregnant.
- to treat infants.
- on patients suffering from renal insufficiency.
- if you are undergoing treatment for chickenpox and/or for herpes zoster; if you took brivudine, sorivudine and/or their derivatives (antiviral medicines for the treatment of herpes zoster).

  The active ingredient, fluorouracil, concomitantly with brivudine, sorivudine or their derivatives, may significantly exacerbate the side effects of Verrumal.

  Treatment with Verrumal may be started, at the very earliest, four weeks after completing the treatment for herpes zoster with brivudine or sorivudine.

  If you are being treated or were recently treated for a herpes zoster infection, inform the doctor about the medicines that you are taking or took.

Verrumal is not intended for application on extensive areas of skin (on more than 25 square centimeters) and the medicine should not come in contact with the eyes or mucous membranes.

Special warnings about using this medicine

Before using Verrumal, tell your doctor:

- if you know that you do not have any activity of the enzyme dihydropyrimidine dehydrogenase (DPD) (complete DPD deficiency).. This enzyme play a significant role in breaking down the active ingredient of the medicine: fluorouracil. A delay or a decrease in the activity of these enzymes (for example, due to the administration of DPD inhibitors such as: brivudine or sorivudine) may lead to an accumulation of the active ingredient, fluorouracil. It is therefore important that you do not apply more Verrumal than indicated in section 3 of this package leaflet.
- when you are taking phenytoin for the treatment of epileptic seizures. Using Verrumal while taking phenytoin may increase the levels of phenytoin in the blood. Therefore, you should regularly monitor the levels of phenytoin in your blood.
- in the instance of warts on areas of thin skin, Verrumal should be applied less frequently; the doctor will examine the treated area more frequently, since it may result in the formation of scars.
- Regular medical examinations are needed if you are suffering from sensory disturbances, pain and an ability to sense temperature (sensory disturbances such as those experienced by diabetes patients).

After applying Verrumal, take care that it does not come in contact with textiles or acrylics (such as acrylic baths). The solution may cause permanent stains.

Do not use Verrumal on bleeding wounds.

Children and adolescents

Do not use Verrumal on infants, because the risk of overdose is higher among children than among adults. Do not exceed the recommended area of treatment or frequency of use, particularly in relation to small children.

Tests and follow-up

It is recommended that you consult with your doctor regularly during treatment with this medicine. Empirically, it has been found that it is recommended in many cases (such as in cases of protruding warts or warts under the soles of the feet) for the doctor to remove the necrotic tissue after the treatment with Verrumal.

Drug interactions

If you are taking or have recently taken other medicines, including nonprescription medications and dietary supplements, tell your doctor or pharmacist. Particularly if you are taking:

- Do not use Verrumal if you are taking or have taken particular antiviral medicines, such as for chicken pox or herpes zoster (brivudine, sorivudine or their derivatives) during the last 4 weeks.
- You must be particularly careful if you are taking anticonvulsants (phenytoin). It is known from systemic use of fluorouracil during cancer treatments that if fluorouracil is administered concomitantly with phenytoin, the phenytoin levels may become elevated.
- Salicylic acid absorption and possible reactions with methotrexate (medicine for the treatment of rheumatic diseases, cancer and severe psoriasis) and sulphonylurea (an ingredient of some of the medicines used to lower the blood sugar level (anti-diabetics)) are possible.

Pregnancy and breastfeeding

If you are pregnant or are breastfeeding, if you think that you may be pregnant or are planning to become pregnant, consult with your doctor or pharmacist before using the medicine.

Do not use Verrumal during breastfeeding, pregnancy or if pregnancy is suspected.

Driving and using machines

No particular means of caution are necessary.

Important information about some of this medicine's ingredients

Verrumal contains dimethyl sulfoxide, which may cause skin irritation.

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

Keep in mind that Verrumal fluid is flammable before a film is formed! Do not light a cigarette or stay near open flames until the film is completely dry.

3. How to use this medicine?

Always use this medicine according to your doctor's instructions.
Check with your doctor or pharmacist if you are not sure about your dose or about how to use this medicine.

Only your doctor will determine your dose and how you should use this medicine.

The recommended dosage is usually:

Apply Verrumal solution two to three times a day on each wart.

Do not apply the medicine on a large area of skin (on more than 25 square centimeters).

The medicine should not come in contact with the eyes or mucous membranes.

This medicine is not intended for infants.

Do not exceed the recommended dose.

Directions for use

Apply Verrumal solution only on the wart itself and not on the healthy skin surrounding the wart. If necessary, you may cover the surrounding skin with a protective oily ointment. If needed, your doctor or pharmacist will recommend a suitable ointment to you.

Open the bottle by pressing down on the cap and turning it in a counter-clockwise direction. It is recommended that you wipe off any extra solution from the bottle neck. In the event of tiny warts, you may apply using a toothpick or similar implement, instead of a brush, in order to ensure precise application. Always remove the residual thin film before each new application of Verrumal.

In the event of a wart around or under a nail, make sure that the nail is intact (is not cracked) in order to prevent the medicine from penetrating the nail bed.

Treatment duration

The average duration of treatment is 6 weeks.

Continue treatment for an additional 7 days after successful healing.

Consult with your doctor or pharmacist if you get the impression that the effect of Verrumal is too strong or too weak.

If areas of thin skin are afflicted by warts, the solution should be applied less frequently than in areas with a normal skin thickness (epidermis), since it may result in the formation of scars.
Close the bottle tightly immediately after use, because the solution dries up quickly if the bottle remains open.

This medicine is intended for external use only.

If you applied more Verrumal than is recommended
please consult with your doctor.

If a child has accidentally swallowed some of the medicine, immediately see a doctor or go to a hospital emergency room and bring the medicine package with you.

If you forget to apply Verrumal
do not apply a double dose in order to compensate for the dose that you forgot.
Continue the treatment as recommended by your doctor.

Adhere to the treatment as recommended by your doctor.
Even if your health improves, do not stop the treatment with this medicine without consulting with your doctor.

If you stop the treatment with Verrumal before completing the course of treatment
please consult with your doctor.

Do not take medicines in the dark! Check the label and dose <u>every time</u> you take medicine. Wear glasses if you need them.

If you have any further questions about using this medicine, consult with your doctor or pharmacist.

4. <u>Side effects</u>

Like with all medicines, using Verrumal may cause side effects in some users. Do not be alarmed by this list of side effects; you may not experience any of them.

Very common side effects affecting more than one in ten users: erythema, inflammation, irritation, burning sensation, pain and itching of the skin at the site of the application.

Common side effects affecting 1-10 in 100 users: bleeding, the formation of a crust and oozing of the skin at the site of the application.
Skin peeling and a reaction of skin erosion (loss of the top layer of skin) are possible.
Headache is possible.

Uncommon side effects affecting 1-10 in 1,000 users: skin inflammation, edema and an ulcer at the site of the application.
An overproduction of tears, itching/tingling and dryness of the eyes are possible.

Rare side effects affecting 1-10 in 10,000 users: an intense burning sensation may necessitate discontinuation of the treatment.

Verrumal contains salicylic acid. This ingredient may cause mild irritation, such as a skin inflammation (dermatitis) or a hypersensitive reaction (allergic reaction upon contact). This irritation may also be expressed by tingling, redness and blisters beyond the treated area.

Whitened skin around the treated wart and desquamation (skin erosion) may occur.

If you experience any side effect, if any side effect gets worse, or if you experience a side effect not mentioned in this leaflet, consult with your doctor.

Reporting side effects

You can report side effects to the Ministry of Health by following the link 'Reporting Side Effects of Drug Treatment' on the Ministry of Health home page (www.health.gov.il), which links to an online form for reporting side effects. You can also use this link: https://sideeffects.health.gov.il.
You can also report by sending an email to the Registration-holder's patient safety unit: drugsafety@neopharmgroup.com.

5. How to store the medicine?

Prevent poisoning! To prevent poisoning, keep this, and all other medicines, in a closed place, out of the reach and sight of children and/or infants. Do not induce vomiting unless explicitly instructed to do so by a doctor.

Do not use the medicine after the expiry date (exp. date) which is stated on the bottle label and on the carton. The expiry date refers to the last day of that month.

Storage conditions

Do not store at temperatures below 10˚C or above 25°C.
Do not use this medicine for more than 6 months after you opened the bottle.
Keep the bottle tightly closed immediately after you open it for the first time; otherwise, the solution dries up quickly and you will not be able to use it properly. Do not use Verrumal if the medicine has dried up. Do not use this medicine if crystals have formed in it.

Caution! Flammable fluid! Keep away from open fire and flames.

Do not throw away medicines via wastewater or household waste. Ask the pharmacist how to throw away medicines that you no longer use. These measures will help protect the environment.

6. Additional information

In addition to the active ingredients, this medicine also contains:

Ethyl acetate, Ethanol anhydrous, Dimethyl sulfoxide, Methacrylic acid methyl ester /methacrylic acid butyl ester copolymer, Pyroxyline.

What the medicine looks like and contents of the pack:

Verrumal is a clear, colorless to light yellow-orange solution provided in a glass bottle at the volume of 13 or 14 ml.

Not all pack sizes may be marketed.

Registration-holder's name and address: Neopharm Ltd., 8 Hashiloach, P.O.B. 7063, Petach-Tikva 49170.

Manufacturer's name and address: Almirall Hermal GmbH, Scholtzstrabe 3, D-21465 Reinbek Hamburg, Germany.

Registration number of the medicine in the Ministry of Health's National Drug Registry: 010-34-24061.

This leaflet was revised in November 2020 according to MOHs guidelines.