

PACKAGE INSERT

PODOFILM ® Topical Solution

FORMULA

PODOFILM Topical Solution contains 25% Podophyllin resin as an active substance. Excipients are Benzoine tincture and Benzoine Sumatra tincture.

PHARMACOLOGICAL PROPERTIES

Pharmacodynamic properties

Podofilm's major effect is based on its acantholytic feature. Its therapeutical effect on wart (verruca) is associated to acantholytic effect. Clear morphological changes occur in epithelial cells. Cytotoxic effect of podopyllin has similarities with colchicine. Podophyllin inhibits mitosis in metaphase stage in epithelial cells. Podophyllin is more effective on small keratinized plantar warts rather than plantar warts. Lytic effect of podopyllin does not spread beyond epidermal cells. Basal layer remains intact and it has minimal effect on corium layer. Consequently, scar doesn't develop following topical administration.

Pharmacokinetic Properties

Topically administered Podofilm has no systemic effect.

INDICATIONS

It is indicated for benign epithelial formations such as venereal warts (condylomata accuminata), common warts (verruca vulgaris), and benign papillomas such as granuloma inguinale and plantar warts.

CONTRAINDICATIONS

In case of known hypersensitivity to any ingredient it is contraindicated.

WARNING /PRECAUTIONS

Podofilm is a potent vesicant and should only be applied by the physician. Physician should be careful about patient selection until he comes skilled in this technique. Since residual pigmentation occurs rarely, site of application should be selected carefully. It is recommended to advise patients about effects and possible results of the treatment. It should not be used near eyes, on face and mucous membranes. Do not use if lesion or surrounding tissue is inflamed or irritated. Do not use on diabetic patients or people with poor blood-circulation, on moles, birthmarks and especially on hair growing warts.

If vaginal condylomata are very extensive, it is recommended to treat half of vagina at one time to prevent severe inflammation and interference with micturition. It shouldn't be forgotten that irritation and tissue damage may increase in large areas and in open wounds in which skin integration is impaired.

It should not be used on young children.

SIDE EFFECTS

Following topical use of Podofilm, urticaria, transient fever, paresthesia, polyneuritis, paralytic ileus, leukopenia, thrombocytopenia, coma, and death have been reported rarely. Local effects include severe necrosis and scarring of the anogenital area, paraphimosis requiring circumcision and pseudoepitheliomatous hyperplasia.

Since Podophyllin is a strong vesicant, it may cause blisters if contact with normal skin or mucous membranes occur. If it is spilled on skin, wash immediately and remove using acetone, alcohol or tape. Then wash immediately with warm soapy water and rinse well. If it is spilled on mucous membrane or eyes, remove the precipitated film and wash with water during 15 minutes. Patients vary in their sensitivity to Podofilm and in rare cases tingling, burning or extreme tenderness may develop. In these cases, tape should be removed and should be washed with cold water for 10 to 15 minutes. If soreness persists, puncture blister using sterile technique, apply antiseptic and cover with a steril bandage. It is advised to treat only 1 or 2 lesions at the first visit.

For external use only.

Use in pregnancy and lactation

Pregnancy category: C

Controlled studies during pregnancy and lactation period has not been conducted.

During these periods, product, as well as other products, should be avoided.

WHEN NOTICED AN UNEXPECTED EFFECT, CONSULT YOUR DOCTOR.

Effect on Driving and Operating Machine

No effect known on ability on driving and operating machine.

DRUG INTERACTIONS

No drug interactions are known

METHOD OF ADMINISTRATION AND DOSAGE

During application of the product be careful about affecting surrounding area. Surrounding skin area should be protected using petrolatum. Don't apply more than 1-2 ml of Podofilm during each treatment.

Anogenital warts (Condylomata accuminata): PODOFILM treatment should be carried out by the physician. Apply the drug carefully on the lesion using a cotton applicator or toothpick. Allow the lesion to dry before the next application. During initial application PODOFILM should be allowed to remain on lesion for 1 hour and then should be washed out. If the initial application doesn't cause inflammatory reaction or pain, PODOFILM can be left on lesion for 4 to 6 hours before being washed off at the following applications. Then the medication should be removed using soap and water carefully. If necessary, reapplication can be done at weekly intervals.

It has been reported that use of Podofilm for cervical warts may lead to a false-positive PAP smear for as long as 6 months following its application.

Common warts: Method A (no curettage): There is no need to cut wart or make pre-treatment prior the wart treatment (in the case of subungual warts nail has to be cut to expose the lesion). Using an ear stick or applicator stick, apply PODOFILM (1 layer only) on the wart and to area of 1-3 mm around wart. Allow to dry for a few minutes. Cover with a piece of nonpermeable plastic adhesive tape. Instruct patient to keep the tape for at least 4 hours (up to 24 hours). Within 24 hours a blister forms which is often painful and inflamed. Have the patient visit for control in 1 to 2 weeks. Remove necrotic tissue and treat any wart tissue remains. Allow tissue to re-epithelialize before retreatment.

Method B (with curettage) Apply the same application procedure as in method A. Patients should be called for control one day after application. Local anesthesia may be necessary. This method has several advantages: Treatment with PODOFILM prior to curettage enhances identification of lesion tissue, increases separability of wart tissue and retreatment is rarely necessary. Patient should come 1 month after treatment for observation (the lesion normally heals completely within 1 to 3 weeks.) The use of a topical antibiotic agent is recommended until healing process complete.

Plantar warts: Avoiding bleeding and cutting viable tissue, remove keratin layer on wart. Using an ear cotton or applicator stick, apply PODOFILM on the wart and 1-3 mm zone around wart. Allow to dry for a few minutes. Cover it, using a nonpermeable bandage. After 48 hours, necrotic tissue should be debrided. If any viable wart tissue remains after debridement, reapply a small amount of PODOFILM and bandage as above. For large lesions 3 or more applications may be necessary. When destruction of wart is complete, the healed site will appear smooth with normal skin lines.

Pain Management: Patient should be informed about possible formation of blister which may be painful but will heal within 2-4 days. A mild analgesic, acetylsalicylic acid or paracetamol containing codeine may be necessary. Patients' PODOFILM sensitivity varies and in rare cases tingling, burning and hypersensitivity may be observed. To reduce pain to minimal level, PODOFILM should be applied in thin layer and patient should be advised to remove the tape and wash the region with cold water for 10 – 15 minutes, in case pain occurs. Till than sufficient penetration of medication will occur. If pain sustains, blister should be opened using sterile techniques. After anaesthetic application, area should be closed by bandage. Until patient's sensitivity to pain is not known, it is advised to treat only one or two warts.

Molluscum contagiosum: Apply a thin film of PODOFILM on each lesion. After 1 week, treat any new lesions and resistant lesions using PODOFILM the same way. Lesion is covered using occlusive tape. After 6-8 hours tape should be removed.

OVERDOSE

Podofilm is a potent vesicant and when applied in more than recommended doses on both normal skin areas and mucous membranes, it may cause blisters and ulcerations.

With application on wide areas systemic exposure may occur.

STORAGE CONDITIONS

Store it below 25 °C in room temperature

Keep it out of reach and sight of children in package

COMMERCIAL PRESENTATION AND CONTENT OF PACKAGE

PODOFILM is presented in 25 ml brown glass bottle in a carton box

REGISTRATION OWNER

ASSOS İlaç, Kimya, Gıda Ürünleri Üretim ve Tic. Ltd. Şti
ÜMRANİYE 34773, ISTANBUL

Manufacturer

Pharmascience Inc. Enterprises Importfab INC on behalf of Paladine Labs.

Registration number

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AVAILABLE WITH A PRESCRIPTION