

# PACKAGE INSERT

## **PODOFILM®**

### Podophyllum resin 25%

*For topical use*

**MEDICINAL INGREDIENT:** Podophyllin 250 mg/mL supplied as Podophyllum resin 25% in an adherent film-forming vehicle.

**NON-MEDICINAL INGREDIENTS:** Benzoin tincture and benzoin sumatra tincture.

**INDICATIONS:** For the removal of benign epithelial growths such as venereal warts (condylomata acuminata), common warts (verruca vulgaris), and benign papillomas such as granuloma inguinale and plantar warts.

**ACTIONS:** Podophyllin is a cytotoxic agent. Its most profound effect is interference with mitosis in the cells of the basal layer of the epidermis.

**CAUTIONS:** Keep out of the sight and reach of children. Podophyllin is an extremely potent vesicant and is to be applied only by the doctor.

It is recommended that care be used in the selection of patients to be treated with PODOFILM and method used, the doctor developing his own experience and technique. To avoid toxicity, it is recommended that applications be limited to small areas of intact skin. Do not use on tongue, eyes and other mucous membranes, such as the inside of the nose, mouth, cervix, vagina or anal canal. Do not use if growth or surrounding area is irritated, infected or reddened. Do not use on diabetics or people with poor blood circulation, nor on moles, birthmarks, or unusual warts with hair growing from them. Do not use in circumstances where the genital warts are either florid with a large surface area or so hemorrhagic that absorption of the toxin is probable. Large areas should not be treated at one time since discomfort may be excessive and systemic absorption may result. Do not use near heat, near open flame, or while smoking.

The use of PODOFILM during pregnancy and/or in nursing mothers is not recommended since there have been no adequate and well controlled studies in the use of Podophyllin in pregnant women or nursing mothers. It is recommended that patients be advised of the effect and the possible results of treatment.

**DOSAGE AND ADMINISTRATION:** Care must be exercised when applying the drug so that the adjacent area is not affected. Normal skin adjacent to the lesion should be protected with petrolatum. Apply no more than 1-2 mL of podophyllin during one treatment. Due to the flammable nature of PODOFILM, patients should avoid smoking or being near an open flame during application and immediately after use.

**MOIST ANOGENITAL WARTS (Condylomata acuminata):** PODOFILM treatment should be an office procedure and should be carried out by the physician. Using a cotton applicator or toothpick, apply the drug carefully to the lesions. Allow to dry before adding the next application. It should be allowed to dry before the patient leaves the office.

The initial application should be allowed to remain in place for one hour then washed off. If the initial application is not unusually inflammatory or painful, PODOFILM may be subsequently left on for four to six hours before being washed off. The medication should then be carefully removed with soap and water. Re-application can be carried out at weekly intervals, if necessary.

**COMMON WARTS: Method A (no curettage):** No cutting or prior treatment is required. Occasionally nails must be trimmed to expose subungual warts to medication. Using a Q-Tip or applicator stick, apply PODOFILM (one layer only) to the wart and a 1-3mm margin around the wart. Allow to dry for a few minutes. Cover with a piece of non-porous plastic adhesive tape, e.g. Blenderm. Instruct patient to keep the tape on for at least four hours (up to 24 hours). Within 24 hours a blister forms which is often painful and inflamed. Have the patient return for observation in one to two weeks. Remove necrotic tissue and treat as before if any viable wart tissue remains. Allow tissue to re-epithelialize before re-treatment.

**METHOD B (with curettage):** Proceed as in Method A except have patient return in one day for curettage (local anesthesia may be necessary). There are several advantages to this method: Treatment with PODOFILM prior to curettage enhances identification of tissue planes, increases separability of wart tissue and re-treatment is rarely necessary. Have the patient return for observation in four weeks (the lesion normally heals completely within one to three weeks). The use of a mild anti-bacterial agent until area heals is recommended.

**PLANTAR WARTS:** Pare away keratin covering the wart, avoid bleeding, avoid cutting viable tissue. Using a Q-Tip or applicator stick, apply PODOFILM to both the wart and a 1-3mm margin around the wart. Allow a few minutes to dry. Secure with non-porous plastic adhesive tape. Leave in place for 48 hours, then debride. If any viable wart tissue remains after debridement, re-apply a small amount of PODOFILM and bandage as instructed above. Repeat treatment over several weeks are often necessary. When destruction of wart is complete, the healed site will appear smooth, with normal skin lines.

**PAIN MANAGEMENT:** Warn the patient that the blister may be painful. Prescribe a mild analgesic, e.g. aspirin with codeine, or acetaminophen with codeine. The tape may be removed and the area soaked in cool water for 10-15 minute periods, as needed, provided sufficient time has been allowed for the medication to penetrate. Local anesthesia may be needed during curettage (Method B).

**MOLLUSCUM CONTAGIOSUM:** Coat each lesion with a thin film of PODOFILM. After one week, treat any new lesions the same way and re-treat any resistant lesions with PODOFILM, this time covering with a small piece of occlusive tape. The tape should be removed in 6 to 8 hours.

**CONTRAINDICATIONS:** Hypersensitivity to Podophyllin. The consumption of alcoholic beverages for several hours after treatment, is to be avoided.

**ADVERSE EFFECTS:** Systemic effects from the topical use of podophyllum resin includes urticaria, transient fever, paresthesia, polyneuritis, paralytic ileus, pyrexia, leukopenia, thrombocytopenia, coma, and death. Local effects include severe necrosis and scarring of the anogenital area, paraphimosis requiring circumcision and pseudoepitheliomatous hyperplasia.

**NOTE:** Podophyllin is a strong vesicant and PODOFILM may produce blisters if it comes into contact with normal skin or mucous membrane. If spilled on skin, wipe off at once, using acetone, alcohol or tape remover. Then wash vigorously with warm soapy water and rinse well. If spilled on mucous membrane or eyes, flush with water, remove the precipitated film, and flush with water for an additional 15 minutes. Patients vary in their sensitivity to Podophyllin and in rare cases tingling, burning or extreme tenderness may develop. In these cases, patient should remove tape and soak the area in cool water for 10 to 15 minutes, repeating as required for relief. If soreness persists, puncture blister using sterile technique, apply antiseptic and cover with a Band-Aid. It is advisable to treat only one or two lesions on the first visit, until the sensitivity of the patient is known. For external use only.

**HOW SUPPLIED:** 25 mL bottle. Content is flammable. Keep away from heat, fire and flame. Close tightly immediately after use. Store at room temperature. Do not leave PODOFILM in direct sunlight.

