

## PACKAGE INSERT

**CANTHACUR-PS®**

(Cantharidin 1%, Salicylic Acid 30%, Podophyllin 5%)  
For topical use

**DESCRIPTION:** CANTHACUR-PS® contains Salicylic acid 30%, Podophyllin 5% and Cantharidin 1% in an adherent film-forming vehicle.

**NON-MEDICINAL INGREDIENTS:** Acetone, castor oil, collodion, ethoxyethanol, ethyl cellulose, polyoxyethylene octyl phenol.

**INDICATIONS:** CANTHACUR-PS is to be used topically for the removal of benign epithelial growths such as warts (verruca vulgaris), especially plantar, mosaic, periungual, and molluscum contagiosum. Recommended for resistant and heavily keratinized warts. Because of the absence of scarring, CANTHACUR-PS is useful for treating exposed areas where cosmetic results are important. Painless application and the absence of instruments make it especially useful for treating children.

**ACTION:** The vesicant action of cantharidin is the result of its primary acantholytic action. Its effectiveness against warts is presumed to result from the "exfoliation" of the tumor as a consequence of its acantholytic action. The lytic action of cantharidin does not go beyond the epidermal cells, the basal layer remains intact and there is minimal effect on the corium. As a result, there is no scarring from topical application. Podophyllin is a cytotoxic agent. Its most profound effect is interference with mitosis in the cells of the basal layer of the epidermis. Salicylic Acid is a powerful keratolytic agent.

**CAUTION:** CANTHACUR-PS is a 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 CANTHACUR-PS and the method used, the doctor developing his own experience and technique. Care should be used in selection of site of application since residual pigmentation may occur (rarely). It is recommended that patients be advised of effect and possible results of treatment. Do not use near eyes, on face, mucous membranes or ano-genital areas. Do not use if growth or surrounding tissue is inflamed or irritated. Do not use on diabetics, or people with poor blood circulation, nor on moles, birthmarks, or unusual warts with hair growing from them. Larger areas should not be treated at one time since discomfort may be excessive and systemic absorption may result. The use of CANTHACUR-PS during pregnancy or in nursing mothers is not recommended since there have been no adequate and well controlled studies in the use of cantharidin in pregnant women or in nursing mothers. Not recommended for use on young children due to difficulties in pain management.

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

**DOSE AND ADMINISTRATION: Method A (without 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 CANTHACUR-PS (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. 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 CANTHACUR-PS 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 antibacterial agent is recommended until area heals.

**Plantar warts:** Pare away Keratin covering the wart, avoid bleeding, avoid cutting viable tissue. Using a Q-tip or applicator stick apply CANTHACUR-PS 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 a week, then debride. If any viable wart tissue remains after debridement, re-apply a small amount of CANTHACUR-PS and bandage as instructed above. Three or more such treatments may be required for large lesions. When destruction of wart is complete, the healed site will appear smooth, with normal skin lines.

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

**Pain Management:** Warn the patient that the blister may be painful, and may last 2-4 days. A mild analgesic such as ASA or acetaminophen, plain or with codeine, may be taken. Patients vary in their sensitivity to cantharidin and in rare cases tingling, burning or extreme tenderness may develop. To minimize the pain, apply a thin film of CANTHACUR-PS over the wart, and instruct the patient to remove the bandage shortly after symptoms begin and soak the area in cool water for 10 to 15 minutes, provided sufficient time has been allowed for the medication to penetrate. If soreness persists, puncture blister using sterile technique, apply antiseptic and cover with an adhesive bandage. It is advisable to treat only one or two lesions on the first visit, until the sensitivity of the patient is known.

**ADVERSE REACTIONS:** The development of annular warts following CANTHACUR-PS therapy has been reported in a small percentage of patients. These lesions are superficial and, although they may alarm some patients, present little problem. Treatment consists of patient reassurance and re-treatment using either CANTHACUR-PS or other procedures. There has been one report of chemical lymphangitis following use of CANTHACUR-PS in combination with salicylic acid plaster.

**Note:** CANTHACUR-PS contains strong vesicants and CANTHACUR-PS 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 in eyes, flush with water, remove the precipitated film, and flush with water for an additional 15 minutes.

**HOW SUPPLIED:** Supplied in a bottle containing 7.5 mL. CANTHACUR-PS is very flammable; keep away from heat, fire and flame. Close tightly immediately after use. Store at room temperature away from heat.



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Questions or concerns?  
Paladin Labs Inc.  
St-Laurent, Quebec H4M 2P2  
1-888-867-7426