DORMER LABORATORIES INC.
TORONTO - MONTREAL

CANTHARONE® AND CANTHARONE® PLUS

HIGH POTENCY WART REMOVERS FOR DOCTOR USE ONLY

THE ORIGINAL AND MOST EFFECTIVE CANTHARIDIN TREATMENT

- Simple office procedure no special instruments required
- A selective procedure not randomly destructive
- Painless application
- Produces a uniform blistering action
- Leaves no permanent scars

CANTHARONE®

- **MOLLUSCUM CONTAGIOSUM**
- **COMMON WARTS**
- **PERIUNGAL WARTS**

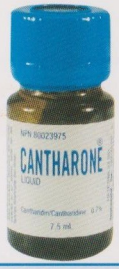
CANTHARONE® PLUS

- **PLANTAR WARTS**
- **RESISTANT & HEAVILY KERATINIZED WARTS**

Each 7.5 ml bottle provides approximately 60 wart treatments

EFFECTIVE WART TREATMENT

Read detailed "Instructions for Use" in each package



GENERAL PRODUCT INFORMATION

CANTHARONE®

NOT RECOMMENDED FOR CHILDREN UNDER 3 YEARS
(PRIOR TO USE, PLEASE READ
THE **"INSTRUCTIONS FOR USE"** FOUND IN EACH PACKAGE)

IMPORTANT: TO BE APPLIED ONLY BY A PHYSICIAN. Due to its toxicity and potential for misuse, CANTHARONE® is not recommended for dispensing or prescribing to patients. Poisonous, may be fatal if ingested. For external use only.

DESCRIPTION: CANTHARONE®, cantharidin collodion is a topical liquid containing 0.7% cantharidin in a film-forming vehicle containing acetone, collodion, castor oil and camphor. The active ingredient, cantharidin, is a vesicant. The chemical name is: Hexahydro-3a,7a-dimethyl-4B,7B-epoxyisobenzofuran-1, 3-dione (C_{10} H_{12} O_4)

INDICATIONS AND USAGE: CANTHARONE® is indicated for removal of common warts, molluscum contagiosum and periungal warts. It is designed for topical application by a physician. Painless application and the absence of instruments makes it especially useful for treating children (some pain may occur later).

CLINICAL PHARMACOLOGY: 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. There are no reports of scarring when cantharidin is used alone as directed, presumably because the lytic action of cantharidin does not go beyond the epidermal cells. The basal layer remains intact and there is minimal effect on the corneum.

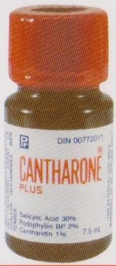
PRODUCT USE

BEFORE USING, PLEASE REVIEW THE WARNING AND CAUTION INFORMATION ON THE BACK

MOLLUSCUM CONTAGIOSUM: On the first visit, treat only a few lesions until the sensitivity of the patients is known, then multiple areas can be treated in one visit. Using a pointed wooden stick, apply a very small amount of solution to only the top of each lesion. Let dry completely. No occlusive tape or dressing is needed (but may be used). Alert patient that blistering is the desired result and that temporary hypopigmentation may occur. The patient may bathe after 4 to 6 hours; sooner if discomfort occurs. Blisters are usually formed by about 24 hours, and crust up in about four days. Mild discomfort or itching can usually be controlled with bathing and night time sedation. In one week, treat any new lesions the same way and retreat any resistant lesions with CANTHARONE®, this time recovering with a small piece of non-porous plastic tape. The tape should be removed in 4 to 6 hours or sooner if discomfort occurs.

COMMON AND PERIUNGAL WARTS: No cutting or prior treatment is required (occasionally nails must be trimmed to expose subungual warts to medication). Using a pointed applicator stick, apply CANTHARONE® directly to the lesion; be sure to cover the growth completely, extending beyond by about 1 mm. Allow a few minutes for a thin membrane to form and cover with a piece of non-porous plastic adhesive tape, e.g. Blenderm®. (taping with occlusive tape is important for full activity). Instruct patient to remove tape in 24 hours and replace with a loose Band-Aid®. On next visit, (1 or 2 weeks), remove necrotic tissue and re-apply CANTHARONE® to any growth remaining. A single application may suffice for normally keratinized skin.

PLANTAR WARTS: Prior to the treatment, thoroughly clean the surrounding skin to assure goodadhesion of the occlusive tape. Proper taping with non-porous plastic tape is an important part of the procedure. Pare away keratin covering the wart; avoid cutting viable tissue. Using a pointed applicator stick, apply CANTHARONE® to both the wart and about 1 to 3 mm margin around the wart. Allow a few minutes to dry. Secure with a non-porous plastic adhesive tape directly on the treatment site. A doughnut pad over the tape may be helpful. Then secure everything in place using additional tape. After 24 hours, the patient may bathe and replace the dressing. Debride one to two weeks after the treatment. If any viable wart tissue remains after debridement, re-apply a small amount of CANTHARONE® and bandage as above. Three or more such treatments may be required for large lesions. For large mosaic warts, treat a portion of the wart at a time. Applying CANTHARONE® to open tissue will result in stinging from the solvent. This can usually be avoided if paring is done carefully and treatments are two weeks apart. When destruction of the wart is complete, the healed site will appear smooth, with normal skin lines.



GENERAL PRODUCT INFORMATION

CANTHARONE® PLUS

NOT RECOMMENDED FOR CHILDREN UNDER 12 YEARS
(PRIOR TO USE, PLEASE READ
THE **"INSTRUCTIONS FOR USE"** FOUND IN EACH PACKAGE)

IMPORTANT: TO BE APPLIED ONLY BY A PHYSICIAN. Due to its toxicity and potential for misuse, CANTHARONE® is not recommended for dispensing or prescribing to patients. Poisonous, may be fatal if ingested. For external use only.

DESCRIPTION: CANTHARONE® PLUS is a topical liquid containing 30% salicylic acid, 2% podophyllin BP, 1% cantharidin in a film-forming vehicle containing 0.5% octylphenylpolyethylene glycol, cellosolve, ethocel, collodion, castor oil and acetone. Salicylic acid is a keratolytic. The chemical name is 2-hydroxybenzoic acid. Podophyllin is a caustic. Its major component, podophyllotoxin (up to 60%) is an anti-neoplastic and roentgomimetic. Cantharidin is a vesicant. The chemical name is hexahydro-3a, 7a-dimethyl-4b, 7b-epoxyisobenzofuran-1, 3-dione. ($C_{10}H_{12}O_4$).
INDICATIONS AND USAGE: CANTHARONE® PLUS is indicated for removal of warts, especially plantar and resistant and heavily keratinized warts. Painless application and the absence of instruments makes it a simple wart treatment procedure. Some pain may occur later. See DOSAGE AND ADMINISTRATION and WARNINGS sections of instructions for use for specific directions for use.
CLINICAL PHARMACOLOGY: CANTHARONE® PLUS is a mixture of three wart removers. The action of salicylic acid is thought to be due to its keratolytic activity in removing wart virus infected epithelial cells, podophyllin has caustic properties causing destruction of tissue and cantharidin has vesicant properties which are thought to exfoliate the wart tumor. The exact mechanism of each of these agents is not known.

PRODUCT USE

BEFORE USING, PLEASE REVIEW THE WARNING AND CAUTION INFORMATION ON THE BACK

TREATING RESISTENT, HEAVILY KERATINIZED & PLANTAR WART WITH CANTHARONE® PLUS

METHOD A (no curettage): Occasionally, nails must be trimmed to expose subungual warts to medication. Using a pointed wooden applicator stick, apply CANTHARONE® PLUS sparingly (one layer only) to the wart and about 1 to 3 mm margin around the wart. (For large mosaic warts, treat a portion of the wart at a time.) 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 8 hours). Within 24 hours a blister forms which is often painful and inflamed. Have the patient return for observation in one to two weeks. During this period the patient may or may not do periodic soaks as the doctor prefers. 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 CANTHARONE® PLUS prior to curettage enhances identification of tissue planes, increases separability of wart tissue and re-treatment is rarely necessary. The lesion normally heals completely within one to three weeks. Have the patient return for observation in four weeks.

SUMMARY OF USE

CANTHARONE® AND CANTHARONE® PLUS

- Both products are very potent, use sparingly. Treatment is at 10 days to 2 week intervals. Delay treatment if inflamed.
- Both products are to be used under occlusion with a non-porous tape, e.g.Blenderm®, occlude no longer than 8 hours with **CANTHARONE® PLUS** and 24 hours with **CANTHARONE®**
- **Note: Tape is not normally used when treating molluscum.**
- Sterile puncture of the blister will help relieve discomfort and should be done at the discretion of the physician.
- Daily soaks are at the discretion of the physician. It is recommended to use a mild anti-bacterial soap until tissue re-epithelializes.

IMPORTANT INFORMATION

CONTRAINDICATIONS: CANTHARONE® & CANTHARONE® PLUS are not recommended for use with diabetics or persons with impaired peripheral circulation.
DO NOT USE NEAR EYES, ON MUCOUS MEMBRANES, IN ANO-GENITAL, INTERTRIGINOUS OR AXILLA AREAS.

ADVERSE REACTIONS: As with all chemical and cryogenic procedures, following CANTHARONE® therapy, superficial annular warts may develop in a small percentage of patients. Patients may become alarmed, however these lesions are superficial and present little problem. There has been one report of chemical lymphangitis following use of cantharidin collodion in combination with salicylic acid plaster. Also, a case of extreme, painful blistering after treatment of multiple axillary lesions has been reported.

PAIN MANAGEMENT: Advise the patient that the blister may be painful. Prescribe a mild analgesic. The tape may be removed and the area soaked in cool water for 10-15 minutes, as needed, provided sufficient time has been allowed for the medication to penetrate. At the option of the doctor the blister may be punctured using a sterile technique and covered with antiseptic and a Band-Aid®.
PROVIDE EACH PATIENT WITH A PATIENT INFORMATION SHEET (Shipped with each order.)

WARNINGS AND CAUTIONS: CANTHARONE® is a strong vesicant, use sparingly. Patients vary in their sensitivity to cantharidin. A more intense reaction is to be expected in patients with fair skin and blue eyes. (Do not treat large areas or multiple lesions before establishing the sensitivity of the patient. Do not re-apply to the same lesion more than once per week. Do not use on already inflamed or irritated tissue). The blister which forms can be painful and inflamed (see PAIN MANAGEMENT section). Defer second treatment if inflammation is intense. In rare cases, tingling, burning or extreme tenderness may develop. In these cases, the 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 a sterile technique, apply antiseptic and cover with a piece of non-porous adhesive tape, e.g. Blenderm®.

PRECAUTION: There have been no adequate or well controlled studies on the use of cantharidin with pregnant or nursing mothers, therefore the use of CANTHARONE® and CANTHARONE® PLUS **IS NOT RECOMMENDED**. Podophylium is suspected to be teratogenic. CANTHARONE® usually produces blisters if it comes in contact with normal skin or a mucous membrane. If spilled on skin, wipe off at once using acetone or alcohol. Then, wash vigorously with warm soapy water and rinse well. If spilled on mucous membrane or in eyes, flush with water, remove precipitated collodion and flush with water for an additional 15 minutes. **Do not use CANTHARONE® in combination with other chemical wart therapy. CANTHARONE® is flammable; keep it away from heat, sparks and flame.**

PRODUCT CARE: The life of your bottle of CANTHARONE® & CANTHARONE® PLUS can be extended by taking a few precautions:

- Before opening completely remove the blue or red safety seal.
- When removing the product from the bottle , with a stick, try to avoid getting liquid on the top lip of the bottle. The liner of the cap seats on this top part of the bottle. THIS IS WHAT FORMS THE AIR TIGHT SEAL. (An improper seal will allow the product to dry out in the bottle).
- Replacing the cap as soon as you are finished using the product will minimize solvent evaporation.

PREFERENCES: For the list of the latest papers published on Cantharidin and wart treatment please visit **www.dormer.com**, click on "physicians enter here", go to the side bar and click on "Wart Removers", click on the blue headline: "click here for Cantharidin Scientific Publications & Reference Listing". Each item has the publication source where you can review either the abstract or the complete paper. The listing is updated as new articles are identified or published.

PRODUCT	HEALTH CANADA REGISTRATION	SIZE/PACKAGE	PRODUCT CODE
Cantharone®	**NPN 80023975**	**7.5 mL bottle**	**9001-975M**
Cantharone® Plus	**DIN 00772011**	**7.5 mL bottle**	**9002-975M**

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