

CANTHARONE® AND CANTHARONE® PLUS

HIGH POTENCY WART REMOVERS FOR DOCTOR'S USE
THE ORIGINAL AND MOST EFFECTIVE CANTHARIDIN TREATMENT

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



CANTHARONE®

- COMMON WARTS
- PERIUNGAL WARTS
- MOLLUSCUM CONTAGIOSUM

● Each 7.5 mL bottle provides approximately 60 wart treatments.

CANTHARONE® PLUS

- PLANTAR WARTS
- RESISTANT & HEAVILY
KERATINIZED WARTS

EFFECTIVE WART TREATMENT

PRODUCT INFORMATION

CANTHARONE®: NOT RECOMMENDED FOR CHILDREN UNDER 3 YEARS.

Description: CANTHARONE®, cantharidin collodion, is a topical liquid containing 0.7% cantharidin in an film-forming vehicle containing acetone, pyroxylin, 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 (C₁₀ H₁₂ O₄).

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 corium,

Indications and Usage: CANTHARONE® is indicated for removal of common warts, molluscum contagiosum and periungual 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). See Dosage and Administration, and Warnings sections, for specific directions on use contained in each package.

PRODUCT USE

BEFORE USING, PLEASE REVIEW THE WARNING AND CAUTION INFORMATION ON THE BACK PAGE TREATING MOLLUSCUM CONTAGIOSUM WITH CANTHARONE®

Important: Treat only a few lesions at the first visit until the reactivity of the patient is known. Then multiple areas can be treated in one visit.

Method:

- 1) Using a wooden applicator stick, apply a very small amount of solution to only the top of each lesion. Let dry. No dressing is needed.
- 2) Do not occlude unless lesions are large or were resistant to the first treatment, (Then occlude with non-porous tape for 4 - 6 hours.)
- 3) Suggest that patient does not bathe for 4 - 6 hours.
- 4) Prescribe medication for cases of night-time discomfort (pain, itching).
- 5) Treat once weekly for new or resistant lesions (usually 2 or 3 treatments).

NOTE: Provide patients with Cantharone patient information sheets to minimize concerns.

Treatment Progression:

No pain on application.

4 Hours: Mild discomfort may occur.

24 Hours: Blistering usually formed by this time.

4 Days: Crusted blisters fall off leaving superficial erosions. Medication may be needed to control night-time itching.

7 Days: Healed with temporary residual erythema.

If there are resistant lesions, treat as before with CANTHARONE®, but this time use non-porous tape to occlude those lesions for 4 - 6 hours. Temporary depigmentation often occurs; but no scarring.

TREATING COMMON & PERIUNGUAL WARTS WITH CANTHARONE®

No cutting or prior treatment is required. (Occasionally, nails must be trimmed to expose subungual warts to medication). Using an applicator stick, apply CANTHARONE® directly to the lesion; be sure to cover the growth completely, extending beyond about 1 mm. Allow a few minutes for a thin membrane to form and cover with a piece of non-porous 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.

TREATING SELECTIVE CASES OF PLANTAR WARTS WITH CANTHARONE®

CANTHARONE® may be used for the treatment of newly developed Plantar warts and on children with Plantar warts. Use the same procedure as with CANTHARONE® PLUS, Method A (see next page). Prior to treatment, thoroughly clean the surrounding skin to assure good adhesion of the occlusive tape. Proper taping with Blenderm® tape is an important part of the procedure. After 24 hours, the patient may bathe and replace the dressing as the doctor instructs. For large mosaic warts, treat a portion of the wart at a time. When destruction of the wart is complete, the healed site will appear smooth, with normal skin lines.

PRODUCT INFORMATION

CANTHARONE® PLUS: NOT RECOMMENDED FOR CHILDREN UNDER 12 YEARS.

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 keratolytic, The chemical name is 2-hydroxy-benzoic acid. Podophyllin is a caustic. It is an extract of the rhizomes and roots of podophyllum peltatum; the major component podophyllotoxin is an anti-neoplastic and roentgomimetic. Cantharidin is a vesicant, the chemical name is hexahydro-3a, 7a-dimethyl-4B, 7B-epoxyisobenzofuran-1, 3-dione.

Action: 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 pharmacological mechanism of each of these agents is not known.

Indications and Usage: CANTHARONE® PLUS is intended for removal of resistant, heavily keratinized and plantar warts. Useful where painless application is desired. See Dosage and Administration, and Warnings sections, contained in each package, for specific direction for use.

PRODUCT USE

BEFORE USING, PLEASE REVIEW THE WARNING AND CAUTION INFORMATION ON THE BACK PAGE TREATING RESISTANT, HEAVILY KERATINIZED & PLANTAR WARTS WITH CANTHARONE® PLUS

Method A: (no curettage) ; no cutting or prior treatment required. Using a wooden applicator stick, apply CANTHARONE® PLUS sparingly (one layer only) to the wart and a 1 -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 or 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. Have the patient return for observation in four weeks. (The lesion normally heals completely within one to three weeks.)

Pain Management: Warn 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 CANTHARONE® PLUS to penetrate. At the option of the doctor, the blister may be punctured using sterile technique and covered with antiseptic and a Band-Aid®. Local anesthesia may be needed during curettage (Method B).

FOR ALL TREATMENTS: SUMMARY OF USE

- 1) Both products are very potent. (CANTHARONE® PLUS is extremely so). Use each sparingly. Treatment is at one and a half to two week intervals. (Delay re-treatment if inflamed.)
- 2) Both products are to be used under occlusion with plastic (non-porous) tape, e.g. Blenderm®, occlude no longer than 8 hours with CANTHARONE® PLUS", or 24 hours with CANTHARONE®". (Note: Tape is normally not used when treating molluscum.
- 3) Sterile puncture of the blister will help relieve discomfort and should be done at the option of the doctor.
- 4) Daily soaks following therapy are at the option of the doctor.
- 5) Antibacterial: It is recommended that a mild anti-bacterial soap be used until the tissue re-epithelializes.

PRODUCT CARE

The life of your bottle of CANTHARONE® or CANTHARONE® PLUS can often be greatly extended by taking a few precautions:

- 1) Before opening, completely remove the blue or red safety seal.
- 2) When removing the product from the bottle (with stick or broken Q-Tip® end) , try to avoid getting liquid on the top of the bottle lip. The liner of the cap seats on this top part of the bottle. THIS IS WHAT FORMS THE SEAL. (An improper seal will allow the product to dry out in the bottle.)
- 3) Replacing the cap as soon as you are finished using the product will minimize solvent evaporation.
- 4) If you notice any crust or dried material accumulating on top of the bottle lip, clean this area off with acetone and disposable wipes. (Scraping may be necessary.) WEAR DISPOSABLE GLOVES.
- 5) Finally, if either product becomes dried out or highly viscous, you may stir in some acetone. If any solids are present, stir with a metal spatula or rod. COMPLETELY REDISSOLVE ANY SOLIDS. Do not over-thin, i.e. use just enough acetone to approximate the original viscosity.

IMPORTANT INFORMATION

WARNING : CANTHARONE® and CANTHARONE® PLUS are TOXIC and are NOT TO BE DISPENSED OR PRESCRIBED for patient administration under any circumstances due to the risk of improper use and to the serious danger of FATAL poisoning if swallowed. FOR EXTERNAL USE ONLY. CANTHARONE® and CANTHARONE® PLUS are flammable: keep away from heat, sparks and flame.

Precautions: There have been no adequate and well-controlled studies on the use of cantharidin in pregnant women or nursing mothers; therefore, the use of CANTHARONE® and/or CANTHARONE® PLUS IS NOT RECOMMENDED during pregnancy or while nursing.

Contraindications: CANTHARONE® and CANTHARONE® PLUS are not recommended for use with diabetics or persons with impaired peripheral circulation. It is not recommended for use near eyes, on mucous membranes, in ano-genital, intertriginous, or axilla areas. See specific direction sheets for more details on Use, Warnings, Precautions and Adverse Reactions.

Adverse Reactions: The development of superficial annular warts in a small percentage of patients, who may become alarmed, may occur following cantharidin therapy. Warning the patient or parent of the possibility prior to treatment alleviates much of their concern. There have been several reports of chemical lymphangitis following use of CANTHARONE®, one in combination with salicylic acid plaster. Also, a case of extreme, painful blistering after treatment of multiple axillary lesions.

CAUTION: 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 REAPPLY TO THE SAME LESION MORE THAN ONCE PER WEEK. DEFER SECOND TREATMENT IF INFLAMMATION IS INTENSE. SHORT TERM RESIDUAL PIGMENT CHANGES MAY OCCUR.

REFERENCES

(1) Kelly, M.G. and Hartwell, J.L., The Biological Effects And Chemical Composition of Podophyllin. A Review, j. Natl. Cancer Inst, 14, 967- 1010, Feb. 1954, (2) Epstein, W.L, and Kligman, A.M., Treatment of Warts with Cantharidin, Arch. Dermat. 77:508, May 1958, (3) Stoughton, R.B. and Bagatell, F., The Nature of Cantharidin Acantholysis, J. Invest. Dermat., 33:287, Nov. 1959. (4) Epstein, J.H. and Epstein, W.L., Cantharidin Treatment of Digital and Periungual Warts, Calif. Med., 93:11, July, 1960, (5) Funt, T.R., Cantharidin Treatment of Molluscum Contagiosum, Arch. Dermat., 83:504, March, 1961. (6) Ormond, C.S., Cantharone, A Cantharidin Tincture as a Useful Agent in Treating intractable Plantar Lesions, J. Amer. Podiat. Assn., 52:427, June, 1962. (7) Perlman, H.H., Let's Talk About Warts, Med. Times 92, 99- 112, Feb., 1964. (8) Bock, R.H., Treatment of Palpebral Warts with Cantharone, Amer. J. Ophthal., 60:529, Sept., 1965. (9) Tromovitch, T.A. and Allen, J.C., Molluscum Contagiosum, Cutis 2:21, Jan., 1966. (10) Curtis, A.C. and Thurston, C.S., What's What About Warts, Cutis 3:1297, Dec. 1967. (11) Basile, O.J., Plantar Warts - A Cantharidin-Occlusive Technique for Treatment, Cutis, 5:1134, Sept. 1969, (12) Dilaimy, M., Letter to the Editor, Arch. Dermat., 111:1073, Aug., 1975. (13) Funt, T.R., Cantharidin: A Valuable Office treatment of Molluscum Contagiosum, J. Southern Med. Assoc., 72:1019, Aug. 1979, (14) Karol, M.D., Suspected Teratogenicity from Topical Application, Clin., Toxicol. 16:283-6, 1980. (15) Epstein, Ernst, Common Skin Disorders, (1988), Medical Economics Co. Inc., New Jersey.

PATIENT INFORMATION SHEETS AVAILABLE UPON REQUEST.

PRODUCT	HEALTH CANADA REGISTRATION	SIZE/PACKAGE	PRODUCT CODE
CANTHARONE® Regular	DIN 00619035	7.5 mL Bottle	9001-975
CANTHARONE® PLUS	DIN 00772011	7.5 mL Bottle	9002-975

(R) 5007

DORMER LABORATORIES INC.

91 Kelfield Street #5

Rexdale, Ontario M9W 5A3

Tel.: (416) 242-6167, Fax: (416) 242-9487

205/5M