PRODUCT RECEPTION, USE & CARE

- Remove the bottle from the container and read the enclosed Instructions For Use.
  Remove the blue safety seal before opening the bottle and discard. Recycle the plastic container.
- CANTHARONE® is flammable. The bottle should be kept away from sunlight, heat, sparks, or flame.
  Product should be stored at room temperature.
- Use a pointed applicator for removal of the product from the bottle for application to each wart. Avoid getting the product on the lip of the bottle which will prevent an airtight seal.
  If product does get on the bottle lip, remove it carefully with a damp paper towel.
  Carefully dispose of the paper towel.
- Close bottle tightly immediately after each application to avoid product evaporation.

PRODUCT	HEALTH CANADA REGISTRATION	BOTTLE SIZE	PRODUCT CODE
CANTHARONE® LIQUID	NPN 80023975	7.5 mL	9001-975M

*CANTHARONE® IS A REGISTERED TRADEMARK OF DORMER LABORATORIES INC.

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Cantharone® Products are not approved for sale or use in the United States

(R) 9001-2608E

DORMER
LABORATORIES INC

CANTHARONE®
LIQUID

Each 7.5 mL bottle provides approximately 60 treatments

HIGH POTENCY WART REMOVER

EFFECTIVE CANTHARIDIN TREATMENT

- **Molluscum contagiosum**
- **Periungual warts**
- **Common warts**
- **Plantar warts**

- Simple office procedure no special instruments required
- Painless application

TO BE APPLIED BY LICENSED HEALTHCARE PRACTITIONERS* ONLY

Read INSTRUCTIONS FOR USE before application

*The treating healthcare practitioner should possess adequate training specific to the treatment of the indicated conditions and the management of adverse events which may arise from use of the product.

GENERAL PRODUCT INFORMATION
PRIOR TO USE, PLEASE READ THE INSTRUCTIONS FOR USE FOUND IN PRODUCT PACKAGE

CANTHARONE®

(not recommended for children under age of 3 years)

MOLLUSCUM CONTAGIOSUM, COMMON WARTS, PLANTAR WARTS

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 periungual warts. Painless application (some pain may occur later) and the absence of instruments makes it especially useful for treating children.

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.

WART TREATMENT REGIMENS

MOLLUSCUM CONTAGIOSUM:

- On the first visit, treat only a few lesions until the sensitivity of the patient is known, then multiple areas can be treated in one visit.
- Using a pointed applicator† stick, apply a very small amount of solution to only the top of each lesion. Let dry completely (2-3 minutes). 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. Mild discomfort or itching can usually be controlled with bathing and nighttime sedation.
- In 1 week, treat any new lesions the same way and retreat any resistant lesions with CANTHARONE®, this time covering with a small piece of non-porous tape*. The tape should be removed in 4 to 6 hours or sooner if discomfort occurs.

COMMON AND PERIUNGUAL 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. Allow a few minutes for a thin membrane to form and cover with a piece of non-porous plastic adhesive tape (taping with occlusive tape is important for full activity). Instruct patient to remove tape in 24 hours and replace with a loose non-plastic tape.
- 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 treatment, thoroughly clean the surrounding skin to assure good adhesion 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 a 1-3 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.

† Pointed applicator could be a plastic one such as coffee straw stirrer or pipette.

* Non-porous tape refers to Blenderm™. It is recommended to secure tape on plantar wart with a Hypafix® type tape.

BLENDERM IS A TRADEMARK OF 3M COMPANY.
HYPAFIX IS REGISTERED TRADEMARK OF BSN MEDICAL LIMITED.

IMPORTANT INFORMATION

CONTRAINDICATIONS: The applications of CANTHARONE® is not recommended for use in diabetics or persons with impaired peripheral circulation. **DO NOT USE NEAR EYE CONTOUR, ON MUCOUS MEMBRANES, IN ANO-GENITAL, INTERTRIGINOUS AND AXILLA REGIONS.**

CANTHARONE® is NOT RECOMMENDED for use with pregnant or nursing women as there have NOT been any adequate or well controlled studies on the use of cantharidin.

WARNINGS AND CAUTIONS: CANTHARONE® is a strong vesicant, use sparingly. Sensitivity to cantharidin varies from patient to patient. A stronger reaction might be expected in patients with fair skin and blue eyes. DO NOT TREAT LARGE AREAS OR MULTIPLE LESIONS BEFORE ASSESSING THE PATIENT'S SENSITIVITY TO THE PRODUCT. DO NOT RE-APPLY MORE THAN ONCE A WEEK TO THE SAME LESION. DO NOT APPLY TO IRRITATED OR INFLAMED TISSUE. The blister that forms is often inflamed and painful (see "PAIN MANAGEMENT" section). Defer second treatment if inflammation is intense. In rare cases, tingling, burning or extreme tenderness may occur. If this happens, the patient should remove the tape and soak the area with cool water for 10 to 15 minutes and repeat as needed to obtain relief. If the pain persists, pierce the blister using a sterile method, apply an antiseptic and cover with a dressing.

PRECAUTIONS: Clinicians should use non-latex gloves while applying Cantharone®.
DO NOT USE CANTHARONE® IN COMBINATION WITH ANY OTHER CHEMICAL WART THERAPY.

Restrict product application to top area of warts. If liquid is spilled on normal skin, wipe it off at once using acetone or alcohol, followed immediately with vigorous washing with warm soapy water, rinsing well. If spilled on a mucous membrane or in eyes, flush with water, remove precipitated collodion and flush with water for an additional 15 minutes.

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. One case of extreme and painful blistering has been reported after treatment of multiple axillary lesions.

PAIN MANAGEMENT:

- Warn the patient that blister may be painful. Prescribe a mild analgesic.
- The tape may be removed and the area soaked in cool water for 10 to 15 minutes as needed, provided sufficient time has been allowed for the medication to penetrate.
- At the discretion of the physician, the blister may be punctured using sterile technique and covered with an antiseptic and a dressing.

POST TREATMENT CARE:

- It is recmmended to use a mild anti-bacterial soap until tissue re-epithelializes.
- Provide patients with a copy of the Cantharone® Patients Information Sheet.

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To be applied by licensed healthcare practitioners ONLY

Do not dispense or prescribe Cantharone® to patients due to toxicity and potential misuse.