PRODUCT RECEPTION, USE & CARE

- Remove the bottle from the container and read the enclosed Instructions For Use.
  Remove the red safety seal before opening the bottle and discard.
- CANTHARONE®PLUS 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® PLUS	DIN 00772011	7.5 mL	9002-975M

*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) 9002-2608E

DORMER
LABORATORIES INC

CANTHARONE®
PLUS

HIGH POTENCY WART REMOVER

EFFECTIVE CANTHARIDIN TREATMENT

- **Plantar & Periungual Warts**
- **Resistant & heavily keratinized 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® PLUS
(not recommended for children under age of 12 years)

RESISTANT, HEAVILY KERATINIZED & PLANTAR WART

DESCRIPTION: CANTHARONE® PLUS is a topical solution containing Salicylic acid 30% (w/v), Podophyllin 2% (w/v), Cantharidin 1% (w/v) in a film-forming vehicle containing octylphenyl polyethylene 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 ($C_{10}H_{12}0_4$).

INDICATIONS AND USAGE: CANTHARONE® PLUS is indicated for removal of warts, especially plantar, periungual, resistant and heavily keratinized warts. Painless application and the absence of instruments makes it a simple wart treatment procedure. Some pain may occur later.

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 due to its acantholytic action. The pharmacological mechanism of action of each of these agents is not well known.

TREATING RESISTANT, HEAVILY KERATINIZED & PLANTAR WARTS

METHOD A (no curettage):
- Occasionally, nails must be trimmed to expose subungual warts to medication. Using a pointed applicator stick, apply CANTHARONE® PLUS sparingly (one layer only) on the top of wart area. (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 adhesive tape.*
- Instruct patient to keep the tape on for at least 4 hours (up to 8 hours).
- Within 24 hours a blister forms which is often painful and inflamed. Have the patient return for observation in 1 to 2 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 1 to 3 weeks.

* Non-porous tape refers to Blenderm™. It is recommended to secure tape on planter 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® PLUS is not recommended for use in diabetics or persons with impaired peripheral circulation. **DO NOT USE NEAR EYES, ON FACE, ON MUCOUS MEMBRANES, IN ANO-GENITAL, INTERTRIGINOUS AND AXILLA REGIONS.**

CANTHARONE® PLUS is NOT RECOMMENDED for use in pregnant or nursing women as there have NOT been any adequate or well controlled studies on the use of cantharidin. Podophyllum is suspected to be teratogenic.

WARNINGS AND CAUTIONS: CANTHARONE® PLUS 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 ON 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® Plus.
DO NOT USE CANTHARONE® PLUS 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® PLUS 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 a licensed healthcare practitioner with adequate training specific to the treatment of the indicated conditions and the management of adverse events which may arise from use of the product.

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