

TOPICAL ANESTHETIC SPRAY

CRYODOSE TA MIST #1802 • MEDIUM STREAM #1803 MEDIUM STREAM MINI #1804 • MIST MINI #1805

Directions For Use

CAUTION: Federal Law restricts this sale by or on the order of a licensed healthcare practitioner. **NOTE:** This product is a medical device and not a Rx drug.

INDICATIONS FOR USE: CryoDose TA Medium Stream and Mist Spray are topical anesthetic sprays – vapocoolants (skin refrigerants) intended for topical application to skin, intact mucous membranes (oral cavity, nasal passageways and the lips) and minor open wounds. CryoDose TA's skin refrigerant controls pain associated with injections (venipuncture, IV starts, cosmetic procedures), minor surgical (lancing boils, incisions, drainage of small abscesses, and sutures), and the temporary relief of minor sports injuries (sprains, bruising, cuts and abrasions).

A PRECAUTIONS:

- 1) Do not spray in eyes.
- 2) Use caution when treating patients with poor circulation or insensitive skin.
- 3) If used to produce local freezing of tissues, adjacent areas should be protected by an application of petroleum.
- The freezing and thawing process may be painful. Freezing may lower resistance to infection and healing.
- Over application may cause frostbite and/or alter skin pigmentation.
- bo not use on large areas of damaged skin, puncture wounds, animal bites or serious wounds.
- 7) Apply only to intact mucous membranes.
- 8) Do not use on genital mucous membranes.

ADVERSE REACTIONS: Freezing can potentially alter skin pigmentation.

CONTRAINDICATIONS: CryoDose TA is contraindicated in individuals with a history of hypersensitivity to 1,1,1,3,3-Pentafluoropropane and 1,1,1,2-Tetrafluoroethane. If skin irritation develops, discontinue use.

WARNINGS: For external use only. Contents under pressure. For use on minor open wounds and intact mucous membranes only.

KEEP OUT OF THE REACH OF CHILDREN. As the safety for the use of the subject device in pediatric patients has not been established, it is recommended that the device should not be used on patients under four years old without the consultation of a pediatrician or other qualified clinician.



TOPICAL ANESTHETIC SPRAY

Directions For Use (continued)

INSTRUCTIONS:

Press actuator button firmly to discharge spray.

If aerosol can stops spraying due to low volume remaining in can, rotate white actuator button approximately ½ turn, then point nozzle at treatment area and press actuator button firmly.

 PRE-INJECTION ANESTHESIA: Have necessary medical supplies ready and prep the procedure site according to facility's protocol. Spray treatment area from a distance of 8-18 cm (3-7 in) continuously for 4-10 seconds or until skin turns white, whichever comes first. Do not spray longer than 10 seconds. After spraying the site, immediately perform the procedure. The anesthetic effect lasts about one minute. Reapply if necessary.

2) COTTON APPLICATION: Have necessary supplies ready. Prepare the procedure site per facility's protocol. Spray a small amount into a cup, for about 10 seconds, or until 5 ml of the product has accumulated. Place a cotton ball, cotton swab or gauze into the cup until it is well saturated and there is no visible product left in the cup. Cotton may also be directly sprayed for 10 seconds to achieve saturation. Immediately after saturation, apply the cotton to the site. Hold firmly on the site for 5-15 seconds and immediately perform the procedure. Reapply as needed. Use this application method on intact skin. If the skin is breached use this application swabs or gauze.

3) TEMPORARY RELIEF OF MINOR ATHLETIC INJURIES: Pain from bruises, contusions, swelling, minor sprains, cuts and abrasions may be controlled with CryoDose TA. Duration of application dose impacts amount of cooling. Use smallest dose needed to produce desired effect. Anesthetic effect rarely lasts more than a few seconds to a minute and generally helps reduce or relieve initial trauma of injury. Spray CryoDose TA on target area continuously for 4-10 seconds from distance of 8-18 cm (3-7 in) until skin turns white, taking care not to frost skin or spraying further. Reapply as needed.

CONTENTS: 1,1,1,3,3-Pentafluoropropane and 1,1,1,2-Tetrafluoroethane (pharmaceutical grade). Product is delivered via HAZMAT-fee free ground shipping.

STORAGE: Do not puncture or incinerate container. Do not expose to heat or store at temperatures above 120°F (49°C).

DISPOSAL: Dispose according to local and national regulations.

HOW SUPPLIED: Aerosol Can - various volumes

Manufactured by Nuance Medical, LLC

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