

Directions
For Use



CRYDOSE™ TA

MEDIUM STREAM / MIST SPRAY

Rx only

TOPICAL ANESTHETIC SPRAY

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 minor surgical procedures (such as lancing boils, incisions, drainage of small abscesses, and sutures), injections (venipuncture, IV starts, cosmetic procedures) and the temporary relief of minor sports injuries (sprains, bruising, cuts and abrasions). The Medium Stream spray is also intended for the treatment of myofascial pain caused by trigger points, restricted motion and muscle tension.

⚠ PRECAUTIONS:

- 1) Do not spray in eyes.
- 2) Use caution when treating patients with poor circulation or insensitive skin.
- 3) Patients may experience pain during thawing.
- 4) Freezing may lower local resistance to infection and delay healing.
- 5) Discharging too much refrigerant may alter skin pigmentation.
- 6) Do 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.

Rx ONLY: Federal law restricts this device to sale by or on the order of a physician.

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 three years old without the consultation of a pediatrician or other qualified clinician.

INSTRUCTIONS:

To apply CryoDose TA, **hold aerosol can upright** over treatment area approximately 8-18 cm (3-7 in) away from application site. Press actuator button firmly to discharge spray.

If aerosol can stops spraying, rotate white actuator button approximately 1/2 turn, then point nozzle at treatment area and press actuator button firmly.

1) PRE-INJECTION ANESTHESIA: Prepare syringe. Swab treatment area with an antiseptic. Spray treatment area with CryoDose TA continuously for 4-10 seconds from a distance of 8-18 cm (3-7 in) until skin turns white. Avoid spraying excess on target area and do not frost skin/area. With skin pulled taut, quickly introduce needle. Reapply as needed. Follow the same procedure for other types of needle insertion procedures, including IV infusion and venipuncture.

Directions For Use – CryoDose TA topical anesthetic spray (cont.)

2) TOPICAL ANESTHESIA IN MINOR SURGERY: Clean operative site with appropriate antiseptic. Apply petroleum jelly to protect adjacent area. Spray CryoDose TA on treatment area continuously for 4-10 seconds from a distance of 8-18 cm (3-7 in) until skin turns white. Avoid spraying excess on target area. Do not make incision if target area appears oversprayed. CryoDose TA anesthetic action lasts a few seconds to a minute. Reapply as needed.

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.

4) SPRAY AND STRETCH TECHNIQUE FOR MYOFASCIAL PAIN (CryoDose TA Medium Stream Spray only): CryoDose TA Medium Stream Spray may be used in management of myofascial pain, restricted motion and muscle tension. Potentially responsive clinical conditions include low back pain (from muscle tension), acute stiff neck, torticollis, acute shoulder bursitis, hamstring tightness, sprained ankle, tight masseter muscles and referred pains due to irritated trigger points. Relief of pain facilitates early mobilization and restoration of muscle function. Effective spray and stretch technique involves evaluation, spraying, and stretching; maximum therapeutic value is derived from a practitioner mastering each step in the sequence.

a) Evaluation: Evaluate and confirm that patient has muscle tension and restricted motion caused by an active, irritated trigger point.

b) Treatment application:

- 1) Assist patient into assuming a comfortable position.
- 2) If spraying near face, shield patient's eyes from discharge.
- 3) Hold can upright. To lessen shock of impact, aim stream to meet skin at acute angle from distance of 30-46 cm (12-18 in).
- 4) Spray in parallel sweeps 1.5-2 cm (.6-.8 in) apart at rate of approximately 10 cm per second (4 in per second). Continue until entire muscle is covered (number of sweeps is determined by size of muscle). Apply spray from muscle attachment over trigger point, through and over reference zone.

c) Stretching: Passively stretch muscle during spray application. Gradually increase force with successive sweeps. As muscle relaxes, smoothly take up slack by establishing a new stretch length. Reach full normal length of the muscle to completely inactivate trigger point and relieve pain. Rewarm muscle and repeat procedure if needed. Apply moist heat for 10-15 minutes following treatment. For maximum efficacy, eliminate factors perpetuating trigger mechanism.

CONTENTS: 1,1,1,3,3-Pentafluoropropane and 1,1,1,2-Tetrafluoroethane



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: NET 115 mL/153 g: CryoDose TA Mist #1802, CryoDose TA Medium Stream #1803; NET 35mL/46g: CryoDose TA Medium Stream Mini #1804, CryoDose TA Mist Mini #1805

Manufactured by Nuance Medical, LLC

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