



HURRI- FREEZE™

TOPICAL ANESTHETIC SPRAY

Directions For Use

CAUTION: Federal law restricts this device to sale by or on the order of a licensed healthcare practitioner.

INDICATIONS FOR USE: Hurri-Freeze™ is a topical anesthetic spray – vapocoolant (skin refrigerant) intended for topical application to skin, intact mucous membrane (oral cavity, nasal passageways and the lips) and minor open wounds. Hurri-Freeze 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).

PRECAUTIONS:

- 1) Do not spray in eyes.
- 2) Use caution when treating patients with poor circulation or sensitive skin.
- 3) If freezing local tissues, apply petroleum jelly to adjacent areas for protection.
- 4) The freezing and thawing process may be painful. Freezing may lower resistance to infection and healing.
- 5) Over-application may cause frostbite and/or alter skin pigmentation.
- 6) Do not use on large areas of damaged skin, puncture wounds, animal bites or other 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: Hurri-Freeze should not be used in individuals with a known hypersensitivity to HFO-1233zd (trans-1-chloro-3,3,3-trifluoropropene) or HFO-1234ze (trans-1,3,3,3-tetrafluoroprop-1-ene). If skin irritation develops, discontinue use.

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

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 consultations of a pediatrician or other qualified clinician.

INSTRUCTIONS: Press spray nozzle firmly to discharge spray.

If the aerosol can stops spraying due to low volume, rotate the nozzle approximately 1/2 turn. Then, point the spray nozzle at the treatment area and press firmly.

1) 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 3–7 in. (8–18 cm) continuously for 3–9 seconds or until skin turns white, whichever occurs first. Do not spray for longer than 9 seconds. After spraying the site, immediately perform the procedure. The anesthetic effect lasts approximately 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 9 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 no visible product remains. Cotton may also be sprayed directly for 9 seconds to achieve saturation. Immediately after saturation, apply the cotton to the site. Hold firmly on the site for 4–14 seconds, then immediately perform the procedure. Reapply as needed. Use this application method on intact skin. If the skin is broken, use this application method only with STERILE, disposable cotton balls, cotton swabs or gauze.

3) TEMPORARY RELIEF OF MINOR ATHLETIC INJURIES: Pain from bruises, contusions, swelling, minor sprains, cuts and abrasions may be controlled with Hurri-Freeze. Duration of application dose impacts amount of cooling. Use smallest dose needed to produce desired effect.

The anesthetic effect lasts approximately one minute and generally helps reduce or relieve the initial trauma of an injury. Spray Hurri-Freeze on target area continuously for 3–9 seconds from a distance of 3–7 in. (8–18 cm) until skin turns white, taking care not to frost skin or spraying further. Reapply as needed.

CONTENTS: HFO-1233zd (trans-1-chloro-3,3,3-trifluoropropene) and HFO-1234ze (trans-1,3,3,3-tetrafluoroprop-1-ene). Product is delivered via HAZMAT-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: Can be disposed of in regular trash or recycle, according to your local waste hauler, once empty.

HOW SUPPLIED: Aerosol can – various volumes.



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