

## **Gebauer's Pain Ease® Product Information**

### **Medium Stream and Mist Spray**

**0386-0008-03 and 0386-0008-02**

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

Hold the can upright while spraying.

**INDICATIONS FOR USE:** Gebauer's Pain Ease Mist and Medium Stream Sprays are vapocoolants (skin refrigerants) intended for topical application to skin, intact mucous membranes (oral cavity, nasal passage ways and the lips) and minor open wounds. Pain Ease controls pain associated with injections (venipuncture, IV starts, cosmetic procedures), minor surgical procedures (such as 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 the eyes.
2. Do not use this product on persons with poor circulation or insensitive skin.
3. When used to produce local freezing of tissues, adjacent skin areas should be protected by an application of petroleum.
4. The freezing and thawing process may be painful, and freezing may lower resistance to infection and delay healing.
5. Over application of the product might cause frostbite and/or 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.

**ADVERSE REACTIONS:** Freezing can occasionally alter skin pigmentation.

**CONTRAINDICATIONS:** Pain Ease 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 only. For use on 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 the age of four years without consultation of a pediatrician.

**INSTRUCTIONS:** Press the actuator button firmly, allowing Pain Ease to spray from the can.

**PRE-INJECTION & MINOR SURGICAL TOPICAL ANESTHESIA:** Have all necessary equipment ready and prepare the procedure site per facility's protocol. Hold the can upright, 3 to 7 inches (8 to 18 cm) from the procedure site, about a can's length away. Spray steadily 4 to 10 seconds or until the skin begins turning white, whichever comes first. Do not spray longer than 10 seconds. After spraying the site,

immediately perform the procedure. The anesthetic effect of Pain Ease lasts about one minute. Reapply if necessary.

\*Apply petrolatum to protect the adjacent area for minor surgical procedures.

**Other Application Methods for Pre-Injection Anesthesia:**

**COTTON APPLICATION:** Have necessary equipment ready. Prepare the procedure site per facility's protocol. Spray Pain Ease 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 with Pain Ease 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 method only with STERILE, disposable cotton balls, cotton swabs or gauze.

**TEMPORARY RELIEF OF MINOR SPORTS INJURIES:** The pain of bruises, contusions, swelling, minor sprains, cuts and abrasions may be controlled with Pain Ease. The amount of cooling depends on the dosage. Dosage varies with duration of application. The smallest dose needed to produce the desired effect should be used. The anesthetic effect of Pain Ease lasts about one minute. This time interval is usually sufficient to help reduce or relieve the initial trauma of the injury. Hold the can upright, 3 to 7 inches (8 to 18 cm) from the target area, about a can's length away. Spray steadily 4 to 10 seconds or until the skin begins turning white, whichever comes first. Do not spray longer than 10 seconds. Reapply if necessary.

**CONTENTS:** 1,1,1,3,3-Pentafluoropropane (HFC 245fa high purity) and 1,1,1,2-Tetrafluoroethane (HFC 134a pharmaceutical grade)

**STORAGE:** Store at room temperature. Do not puncture or incinerate container. Do not expose to heat or store at temperatures above 50°C (120°F).

**DISPOSAL:** Dispose of in accordance with local and national regulations.

**HOW SUPPLIED:** Aerosol Can

Manufactured by:

Gebauer Company

Cleveland, OH 44128

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