

Frequently Asked Questions

When do I use Pain Ease?

Gebauer's Pain Ease[®] is an instant topical anesthetic skin refrigerant (vapocoolant) cleared by the FDA to temporarily control pain associated with needle procedures and minor surgical procedures such as: immunizations, allergy injections, foreign body removal, suturing and suture removal, IV starts, and blood draws. Pain Ease can be applied to intact skin, minor open wounds, and intact oral mucous membranes. It is non-drug, non-flammable, and can be used by any licensed healthcare practitioner without the order of a physician.

What is a vapocoolant and how does it work?

Pain Ease is categorized by the FDA as a vapocoolant. Pain Ease is considered a vapocoolant because it creates an instant significant temperature drop on the skin surface site by immediate evaporation. The coldness created by evaporation of the spray decreases the nerve conduction velocity of the C fibers and A-delta fibers that make up the peripheral nervous system. This interrupts the nociceptive inputs to the spinal cord creating a temporary anesthetic effect resulting in procedural pain reduction. (*Lehmann, J. & Delateur, B. Therapeutic Heat and Cold, 4th Edition; Baltimore, Williams and Wilkins; 1990*)

What is in Pain Ease?

Gebauer's Pain Ease consists of a proprietary blend of non-flammable hydrofluorocarbons: 1,1,1,3,3-Pentafluoropropane (high purity HFC-245fa) and 1,1,1,2-Tetrafluoroethane (pharma grade HFC-134a).

I usually don't use anything for patient comfort before needle procedures so why should I use Pain Ease?

Offering a patient Pain Ease to instantly control procedural pain and improve comfort is an easy way to positively impact patient satisfaction. Controlling patient pain and anxiety also helps the healthcare practitioner provide better care and helps the patient have a positive perception of the care they receive, both of which can have a positive effect on CAHPS scores.

A recent study of 300 patients and their healthcare providers found that both patients and healthcare providers felt they had significantly less pain than with prior PIV insertions. In addition, 89.3% healthcare providers and 83.3% of patients would use Pain Ease in the future to lessen the pain of venipuncture. (*Barbour T, O'Keefe S, Mace, S. Patient/Provider Responses – Prospective, double-blind Randomized Study. Western Journal of Nursing. 2020, Dec. 8.*)

How do I use Pain Ease?

Using Pain Ease is as easy as 1-2-3:

1. <u>Prep</u>

Read product instructions prior to use. Have all necessary equipment ready and prepare the skin per your facility's protocol. Educate the patient about the cold effect and inform





them the spray is cold. Prior to spraying the procedure area, give the patient a quick spray of Pain Ease to acquaint them with the vapocoolant sensation.

2. <u>Spray</u>

Hold the can 3 to 7 inches from treatment site. Spray steadily for 4 to 10 seconds or until the skin begins turning white, whichever comes first. Application time will vary between individuals. Do not spray longer than 10 seconds.

3. <u>Perform</u>

Immediately perform the procedure. The anesthetic effect lasts approximately one minute. Reapply if necessary.

Are there other ways to apply Pain Ease to the skin?

As an alternative to spraying directly on the skin, Pain Ease may be applied using a cotton ball, cotton swab or gauze.

- 1. Have the necessary equipment ready. Prepare the procedure site per facility's protocol.
- 2. Spray Pain Ease into a cup for about 10 seconds, or until 5 ml of the product has accumulated.
- 3. 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.
- 4. 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.

Cooling effect studies performed by Gebauer Company demonstrate the temperature of Pain Ease when applied by cotton ball, cotton swab, or gauze for pre-injection anesthesia is substantially equivalent to spraying the product directly on the skin.

How long does Pain Ease last?

The anesthetic property of Pain Ease lasts for up to 60 seconds. Pain Ease can be reapplied as necessary. (Cold Perception, Surface, Subcutaneous and Intramuscular Temperatures Produced by Gebauer Pain Ease[®] Topical Vapocoolant Spray. Merrick MA, Martin KM. Journal of Athletic Training, 47(3), ^oSupplement, 91; May 2012)

Is Pain Ease Sterile?

Pain Ease is not sterile. However, Pain Ease has undergone microbial testing by an independent laboratory to determine total aerobic microbial count, total mold and yeast count, and to demonstrate the product has met USP<61> and USP<62> Microbiological Examination of Non-Sterile Products testing standards. The results demonstrated that Pain Ease is free from Staphylococcus aureus, Pseudomonas aeruginosa, Bacillus subtilis, Clostridia, Escherichia coli, Salmonella, and Candida albicans and is safe to be used prior to aseptic procedures. Additionally, a published clinical trial concludes Pain Ease will not introduce or add microorganisms to a site prepped with an antiseptic. (*Dermatol Surg. 2014 Oct; 40 (10):1103-7. Skin sterility after application of a vapocoolant spray. Schleicher WF, Richards BG, Huettner F, Ozturk C, Zuccaro P, Zins JE*)





How do I clean a can of Pain Ease?

Pain Ease is an FDA cleared multiple-patient reusable device. Gebauer Company does not make recommendations about cleaning of the device as every facility has individual protocols related to handling non-sterile products between uses or between patients. Facilities can follow the recommendations described in the 2008 CDC publication entitled "Guideline for Disinfection and Sterilization in Healthcare Facilities" which includes the Spaulding Classification of medical devices and recommended cleaning. However, it should be noted, our product does not fit into the Spaulding Classification as it never comes in direct contact with the skin surface/patient.

Can Pain Ease be used with children?

Pain Ease is FDA cleared for general use. However, it is recommended that the pediatrician be consulted before using Pain Ease on children four years of age and younger. We do not have approval for use on Neonates.

Can Pain Ease be used during pregnancy?

Gebauer's Pain Ease is safe for use during pregnancy when used as directed. Studies performed on rats showed that 1,1,1,2-Tetrafluoroethane and 1,1,1,3,3-Pentafluoropropane were non-teratogenic and did not cause fetal effects at levels of 50,000 ppm.

Are there any contraindications for using Pain Ease?

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. Consult the product insert for a full listing of all contraindications, warnings, adverse reactions, and precautions.

Can Pain Ease be used with patients who have insensitivities or sensitivities to cold?

Do not use Pain Ease on persons with poor circulation or insensitive skin. Use professional discretion when spraying on patients with insensitivities such as neuropathies, or conditions such as sickle cell anemia or Raynaud's disease that cause them to be sensitive to the cold.

Is a doctor's order required to use Pain Ease in the healthcare setting?

Pain Ease does not need a doctor's order to be used on a patient in a healthcare setting.

Pain Ease is a prescription-only medical device meaning it can be sold to and used by any healthcare practitioner who is licensed in the state in which they practice.

Pain Ease can be purchased by a patient who receives a prescription or "other order" from a licensed healthcare provider.

Is Pain Ease available in different size cans?

Pain Ease Medium Stream and Mist Spray are available in both 3.9 fl. oz. and 1.0 fl. oz. cans. The 3.9 fl. oz. cans have approximately 52 applications. The 1.0 fl. oz. cans have





approximately 10 applications and are designed for use with a single patient, or for when it is more convenient to carry a smaller can.

How do I decide if I should use Pain Ease Medium Stream or Pain Ease Mist?

Using Pain Ease Medium Stream or Pain Ease Mist Spray is the choice of the healthcare practitioner or defined by your facility's procedure protocol. Pain Ease Medium Stream is our most popular spray. Pain Ease Medium Stream can be directed to an exact location making it ideal for procedures such as: IV starts, blood draws, injections, incision, and drainage of small abscesses, suturing, and suture removal. Pain Ease Mist Spray is useful for broader application sites and facial applications. Pain Ease Mist Spray may cause a more intense cooling effect than Medium Stream due to faster evaporation.

What is the expiration date of Pain Ease after it has been applied to a patient?

The date of expiration is found on the bottom of the can in month-year (MM-YYYY) format. Pain Ease is regulated by the FDA as an unclassified medical device and therefore does not fall under the Joint Commission standards for expiration dates of open bottles/vials of medication.

Is Pain Ease flammable?

Pain Ease is non-flammable. It can be used in conjunction with ultrasound, x-ray, laser, and cautery equipment.

Gebauer Company is happy to answer any questions you have about our Pain Ease product. Please contact us at: <u>www.Gebauer.com</u> or Customer Service: 216.581.3030/800.321.9348

