

Gebauer's Ethyl Chloride Topical Anesthetic Spray

Rx Only.

INDICATIONS FOR USE:

Gebauer's Ethyl Chloride Topical Anesthetic Spray (Mist Spray, Fine Spray and Medium Spray): A vapocoolant (skin refrigerant) intended for topical application to control pain associated with injections (starting IV's and venipuncture), minor surgical procedures (such as lancing boils, or incision and drainage of small abscesses), and the temporary relief of minor sports injuries. The Fine and Medium Sprays are also intended for the treatment of myofascial pain caused by trigger points, restricted motion and muscle tension.

PRECAUTIONS: Do not spray in eyes. Use in a well-ventilated area. Intentional misuse by deliberately concentrating or inhaling the contents can be harmful or fatal.

Ethyl chloride is FLAMMABLE and should never be used in the presence of an open flame or electrical cautery equipment.

ADVERSE REACTIONS: Cutaneous sensitization may occur but appears to be extremely rare. Over application of the product may lead to frostbite and/or altered skin pigmentation.

CONTRAINDICATIONS: Ethyl Chloride is contraindicated in individuals with a history of hypersensitivity to it.

(Warning Symbol) WARNINGS: For external use only. Do not spray in the eyes. Skin absorption of ethyl chloride can occur; no cases of chronic poisoning have been reported.

WARNING: This product can expose you to ethyl chloride, which is known to the State of California to cause cancer. For more information go to www.P65Warnings.ca.gov.

KEEP OUT OF THE REACH OF CHILDREN

DIRECTIONS FOR USE (Glass Bottle): To apply Gebauer's Ethyl Chloride from a bottle, hold the bottle inverted while spraying. Open the dispenseal spring valve completely allowing the ethyl chloride to flow from the bottle.

DIRECTIONS FOR USE (Accu-Stream 360):

1. Turn the blue locking ring counterclockwise in the direction of the OPEN arrow.
2. Aim spray at the intended area. CAUTION: Can sprays from the top. Do not spray in eyes. Do not unintentionally aim towards the face.
3. To spray the product, fully depress the handle.

4. The can may be sprayed at any angle, upright, upside down, and any angle in between. Note that when the can is almost empty, the last sprays will only exit the can when the can is in an upright position.
5. Turn the blue locking ring clockwise in the direction of the CLOSE arrow.

DIRECTIONS FOR USE (Mist): To apply Gebauer's Ethyl Chloride from the aerosol can, hold can upright over the treatment area and depress the valve completely allowing Gebauer's Ethyl Chloride to spray from the can. If the aerosol can quits spraying, turn the white actuator button approximately ½ turn, then point the nozzle at the treatment area and press the actuator button firmly.

USES:

1. **PRE-INJECTION & MINOR SURGICAL TOPICAL ANESTHESIA:** Have all necessary equipment ready and prepare procedure site per facility's protocol. Spray the treatment area with Gebauer's Ethyl Chloride from a distance of 3 to 9 inches (8 to 23 cm). Spray steadily for 3 to 7 seconds (aerosol can 4 to 10 seconds) or until the skin begins turning white, whichever comes first. After spraying the site, immediately perform the procedure or introduce the needle. The anesthetic effect of Ethyl Chloride lasts about one minute.
2. **TEMPORARY RELIEF OF MINOR SPORTS INJURIES:** The pain of bruises, contusions, swelling, and minor sprains may be controlled with Gebauer's Ethyl Chloride. 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 Ethyl Chloride lasts about one minute. This time interval is usually sufficient to help reduce or relieve the initial trauma of the injury. Spray the affected area from a distance of 3 to 9 inches (8 to 23 cm) for 3 to 7 seconds (aerosol can 4 to 10). Stop spraying when the skin begins turning white, or 7 (aerosol can, 10) seconds has elapsed, whichever comes first. Avoid spraying beyond this state. Use as you would ice.
3. **SPRAY AND STRETCH TECHNIQUE FOR MYOFASCIAL PAIN (stream sprays only):** Gebauer's Ethyl Chloride may be used as a counterirritant in the management of myofascial pain, restricted motion and muscle tension. Clinical conditions that may respond to Gebauer's Ethyl Chloride include low back pain (due to tight muscles), acute stiff neck, torticollis, acute bursitis of the shoulder, tight hamstrings, sprained ankle, tight masseter muscles and referred pains due to irritated trigger points. Relief of pain facilitates early mobilization and restoration of muscle function. The Spray and Stretch Technique is a therapeutic system that involves three stages: Evaluation, Spraying and Stretching. The therapeutic value of the Spray and Stretch technique is most effective when the practitioner has mastered all of the stages and applies them in the proper sequence.

a. Evaluation:

If the patient has been evaluated to have pain caused by an active, irritated trigger point then proceed to Step b.

b. Spraying:

- 1) Have the patient assume a comfortable position.
- 2) Take precautions to cover the patient's eyes, nose and mouth if spraying near the face.
- 3) Hold the bottle inverted. From a distance of 12" to 18" (30 to 46 cm), aim the stream so it meets the skin at an acute angle, lessening the shock of impact.
- 4) Direct the spray in parallel sweeps 0.5 inches to 1 inch (1.5 to 2 cm) apart at the rate of approximately 4 inches per second (10 cm per second). Continue until the entire muscle has been covered. The number of sweeps is determined by the size of the muscle. The spray should be applied from the muscle attachment over the trigger point, through and over the reference zone.

c. Stretching:

Passively stretch the muscle during spray application. Gradually increase the force with successive sweeps. As the muscle relaxes, smoothly take up the slack by establishing a new stretch length. It is necessary to reach the full normal length of the muscle to completely inactivate the trigger point and relieve the pain. Rewarm the muscle. If necessary, repeat the procedure. Apply moist heat for 10 to 15 minutes following treatment. For lasting benefit, eliminate any factors that perpetuate the trigger mechanism.

Representative units of Gebauer's Ethyl Chloride have been evaluated for biocompatibility according to the ISO 10993 standards for devices in contact with intact skin for limited contact duration. Tests include cytotoxicity, sensitization and irritation and produced passing results.

Testing was performed in accordance with USP <51> Antimicrobial Effectiveness Testing, to demonstrate that the product acts as its own preservative and does not support growth of microorganisms during use.

CONTENTS: Ethyl Chloride

HOW SUPPLIED: 3.9 fl. oz. (116 mL) multi-patient reusable bottle or can.

STORAGE: Contents under pressure. Store in a cool place. Do not store above 120°F (50°C). Do not use near fire or flame or place on hot surfaces.

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

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

Products Made in the U.S.A

SPEC-1517.1
Attachment 4.1

Manufactured by:
Gebauer Company
Cleveland, OH 44128
1-800-321-9348
www.Gebauer.com
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