

GEBAUER'S SPRAY AND STRETCH®

Topical Aerosol Skin Refrigerant

Description

Gebauer's Spray and Stretch is a topical aerosol skin refrigerant that consists of a proprietary blend of 1,1,1,3,3-Pentafluoropropane and 1,1,1,2-Tetrafluoroethane that produces an instantaneous cooling effect upon contact with the skin. The product is delivered in the form of a fine stream spray. Upon contact with the target area the product evaporates immediately leaving no residue. Gebauer's Spray and Stretch is a replacement for Gebauer's Fluori-Methane® and is intended for use with the Spray and Stretch method used in trigger point therapy to control myofascial pain and for control of pain due to minor sports injuries.

Gebauer's Spray and Stretch is non-flammable and non-ozone depleting.

Mechanism of Action

There are several theories documented in the medical literature that provide an explanation for the mechanism of action that makes vapocoolant sprays effective when used with the Spray and Stretch technique.

One of the theories most widely accepted by the physical therapy community is based on the work of Janet Travell and David Simons (Travell and Simons 1983). Their theory surmises that the tactile stimulation produced by the changing gradient of the skin temperature and the impact of the product transmits a continuing barrage of impulses to the spinal cord. This barrage of impulses from the afferent nerves of the skin blocks the trigger point impulse activity by "jamming the spinal switchboard" so that the muscle

sensation becomes disconnected. There are physiological principles that explain these effects including spinal inhibition, descending inhibition and trigger point inhibition.

Spinal Inhibition: As a stream of skin refrigerant contacts the target area it induces a sudden change in the cold, touch and pain sensory modalities of the skin. As the spray is swept along the muscle, a new group of receptors are being sequentially stimulated. The continuing barrage of alarming stimuli from new receptor sites is responsible for the orientation reflex of the central nervous system. By orienting the nervous system to receive the input from the skin sensory modalities, the muscle spasm and pain reflexes are greatly inhibited (Sokolov 1963).

Descending Inhibition (Gate Control Theory): Descending inhibition or the gate control theory of pain is based on the assumption that activation of descending analgesia producing systems accounted for the relief of pain. Thus, when skin refrigerant is applied to the target area, modulation of sensory nerve impulses by inhibitory mechanisms at and above the spinal level are created (Melzack 1973).

Trigger Point Inhibition: Application of Gebauer's Spray and Stretch creates sensory input to the skin that turns off the central nervous system feedback mechanism, which sustains the trigger point activity (Travell and Simons 1983).

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Indications and Use

Gebauer's Spray and Stretch is a vapocoolant (skin refrigerant) intended for topical application in the management of myofascial pain, restricted motion, muscle spasm and minor sports injuries. Gebauer's Spray and Stretch is also intended to control pain associated with injections.

Contraindications

Gebauer's Spray and Stretch 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.

The contents are under pressure. Do not puncture or incinerate the container.

Store at room temperature. Do not expose to heat or store at temperatures above 50°C (120°F).

Dispose of in accordance with local and national regulations.

Keep out of reach of children.

Adverse Reactions

Freezing can occasionally alter skin pigmentation. Injury to the skin due to extreme cold or irritation may create post-inflammatory hypopigmentation due to death of melanocytes in the epidermal layer of the skin. This reaction may be more apparent in people with dark complexions (Taylor 1997).

It often takes several months for the skin pigment to return to its unaltered state. The effects of post-inflammatory hypopigmentation may be permanent (Goodheart 1999).

Precautions

The following precautions should be observed when using Gebauer's Spray and Stretch:

1. Do not spray near the face or on open wounds or abraded skin. If the product should come into contact with the eyes, rinse the eyes with copious amounts of lukewarm water for 15 minutes, lifting the eyelids to facilitate irrigation. See a physician.
2. Do not use this product on diabetics or persons with poor circulation or insensitive skin. Use of cold products on these patients may cause discomfort, skin irritation and/or frostbite. If irritation occurs, rinse the affected area with copious amounts of lukewarm water. See a physician if symptoms persist.
3. Over application of the product might alter skin pigmentation.

Biocompatibility

All biocompatibility and toxicology testing was performed in accordance with ISO 10993 Guidelines and the FDA's Blue Book Memorandum G-95. All testing was performed by independent testing laboratories.

Cardiac Sensitization: 1,1,1,3,3-Pentafluoropropane and 1,1,1,2-Tetrafluoroethane are known to

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be cardiac sensitizers when inhaled in quantities greater than 80,000 ppm (Rusch, Combs, and Hardy 1995) and 44,000 ppm (Talmage, Rusch, Benson, and Stoll 1998) respectively. In studies performed on beagle dogs, fatal ventricular fibrillation was seen at 74,000 ppm, one incident of ventricular defibrillation occurred at 44,000 ppm, and no incidents of cardiac sensitization were seen at 34,100 ppm for 1,1,1,3,3-Pentafluoropropane (Rusch, Combs, and Hardy 1995).

Cytotoxicology: Gebauer's Pain Ease was tested for cytotoxicity in accordance to ISO 10995-5, *Tests for Cytotoxicity – In Vitro Tests* and was found to be non-toxic when used as recommended. Acute cytotoxicity of the product was tested by observing the % inhibition of the cell viability of human keratinocyte HaCat cells when Gebauer's Pain Ease was "sprayed" on the cells for both 5 seconds and 15 seconds and incubated at 5% CO₂ and 37°C. Neither the 5 second nor the 15 second dosage was found to be cytotoxic and had little effect on the HaCat cell viability.

Dermal Sensitization: A dermal sensitization study was performed in accordance with ISO 10993-10, *Tests for Irritation and Sensitization* on guinea pigs using a modified Buehler method to determine the dermal sensitization in the guinea pig with repeated dermal exposure of Gebauer's Spray and Stretch. The animals were exposed to the product three times a week for three weeks. The animals remained in good health throughout the induction phases and no abnormal clinical findings were observed. There was slight erythema noted in one animal at the first induction exposure. There were no incidents of

edema noted during the induction phases. During the challenge phase of the study, one animal had minimal erythema at the 24 hour stage. No incidents of edema were observed during the challenge stage. Based on these results, Gebauer's Spray and Stretch did not produce dermal sensitization in guinea pigs under the conditions of the study.

Acute Dermal Toxicity: An acute dermal toxicity study was performed in accordance to ISO 10993-11, *Tests for Systemic Toxicity* on Sprague-Dawley Rats to determine the acute dermal toxicity of Gebauer's Spray and Stretch. No animals died during the study and the animals gained weight as expected. Observations made at 1 hour, 2.5 hours, 4 hours, 1 day and daily up to 14 days showed no clinical effects as a result of the treatment. Necropsy of the tissues at the end of the study were found to be grossly normal. Gebauer's Spray and Stretch does not produce acute dermal toxicity.

Effects on Fertility: Gebauer's Spray and Stretch 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. Rats exposed daily to levels of 50,000 ppm 1,1,1,2-Pentafluoropropane for six hours from day 6 to day 19 of gestation at the 50,000 ppm level had a reduction in body weight and food consumption. No significant effects were seen on fetal parameters. Pup weight, litter size and uterine weights were slightly reduced when compared to controls. The incidents of malformation, skeletal and

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visceral anomalies and skeletal variants was comparable to the control group (Rusch, Coombs, and Hardy 1995). When exposed daily to 300,000 ppm of 1,1,1,2-Tetrafluoroethane during day 6 through 15 of gestation, there was a significant reduction in fetal weight and increase in skeletal variations (Collins, Rusch, Sato, Hext, and Millischer 1995).

Carcinogenesis: Gebauer's Spray and Stretch is not carcinogenic. When 1,1,1,2-Tetrafluoroethane was administered to rats for 104 weeks, there was a slight increase in the incidence of testicular Leydig cell adenomas in the male rats. This type of tumor does not progress to malignancy in humans, and the lack of genotoxicity support the conclusion that 1,1,1,2-Tetrafluoroethane is not carcinogenic (Collins, Rusch, Sato, Hext, and Millischer 1995). Genotoxicity in 1,1,1,3,3-Pentafluoropropane has not been shown, and various inhalation studies have produced no carcinogenic effects (Rusch, Coombs, and Hardy 1995).

Performance

The Gebauer Company has executed the following performance testing to verify that Gebauer's Spray and Stretch provides a safe and effective product.

Number of Applications: Gebauer's Spray and Stretch products have approximately 50 doses per can when applied for an average time of 10 seconds per dose.

Chemical Compatibility: Chemical compatibility testing performed by the manufacturer's of 1,1,1,3,3-Pentafluoropropane and 1,1,1,2-

Tetrafluoroethane to determine the chemical stability of the Gebauer's Spray and Stretch blend. In chemical stability studies, both 1,1,1,3,3-Pentafluoropropane and 1,1,1,2-Tetrafluoroethane were found to be stable at temperatures up to 400°F.

A mixture of 1,1,1,3,3-Pentafluoropropane and 1,1,1,2-Tetrafluoroethane was stored in a tin-plated aerosol can with a valve and dip tube for a period of two months in ambient conditions. Results from GC/MS analysis confirmed that there were no new compounds formed during the storage due to chemical incompatibility.

Accelerated Stability Studies:

Accelerated stability studies were conducted to determine the chemical stability and packaging integrity of Gebauer's Spray and Stretch in accordance to Q1A Stability Testing Of New Drug Substances and Products, ICH Guidance for Industry; Rev. 1, August 2001. The accelerated stability testing was performed over a period of three months. The products were stored in a controlled environment at 40°C and 75% relative humidity. The following analyses were performed: USP <601> % leak rate, appearance, ratio composition, and % purity. See Table 1 for a summary of the results.

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Table 1
Results of Accelerated Stability Testing for Gebauer's Pain Ease

	USP <601> % Leak Rate	Appearance	Ratio Composition	% Purity
Control	N/a	N/a	Pass	99.99
One Month	<0.5%	No change observed.	Pass	99.99
Two Month	<0.5%	No change observed.	Pass	99.98
Three Month	<0.5%	No change observed.	Pass	99.98

Based on the results of the accelerated stability testing, Gebauer's Spray and Stretch is determined to be chemically stable over time, and does not show evidence of substantial leakage through the valve that may cause the product to malfunction before the expiration date.

Material Compatibility: Material compatibility data for the following materials has been performed with Gebauer's Spray and Stretch in order to show package integrity. Results of the compatibility analysis can be found in Table 2:

Table 2
Material Compatibility of Gebauer's Pain Ease

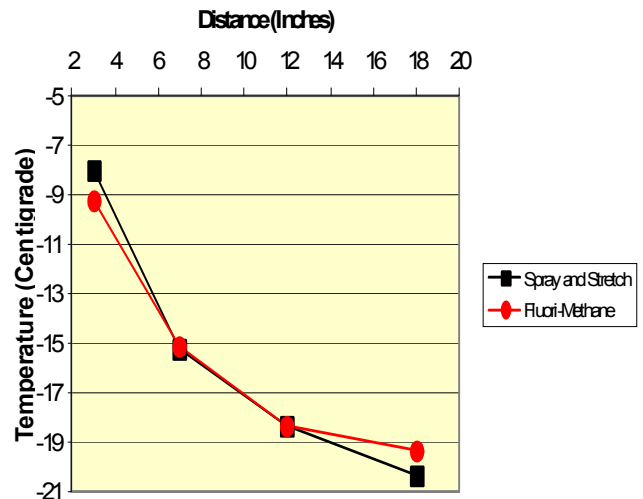
Material	Compatibility
Butyl	Excellent
Poly-propylene	Excellent
Poly-ethylene	Excellent
Acetal	Excellent
Nylon	Excellent
Epoxy	Excellent
Buna N	Excellent

The packaging materials showed excellent material compatibility characteristics. Based on the results, there was no evidence of leachables or

breakdown of the packaging components that would lead to contamination or product malfunction.

Cooling Effect: The cooling effect of Gebauer's Spray and Stretch was compared to the cooling effect of Gebauer's Fluori-Methane, formerly the most widely used product for trigger point therapy. Results of the cooling effect study can be seen in Graph 1:

Graph 1
Cooling Effect of Gebauer's Spray and Stretch vs. Gebauer's Fluori-Methane at Varying Distances



*All testing was performed on validated laboratory equipment.

Based on the results of the analysis, the cooling effect of Gebauer's Spray and Stretch was shown to be substantially equivalent to Gebauer's Fluori-Methane at distances between 3 and 18 inches.

Dosage and Administration

To apply Gebauer's Spray and Stretch from the fine stream aerosol can, hold

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the can upright over the treatment area. Press the actuator button firmly, allowing Gebauer's Spray and Stretch to spray from the can.

Spray and Stretch technique for Myofascial Pain: Gebauer's Spray and Stretch may be used as a counterirritant in the management of myofascial pain, restricted motion and muscle tension. Clinical conditions that may respond to Spray and Stretch include low back pain (due to tight muscles), acute stiff neck, torticollis, acute bursitis of the shoulder, tight hamstrings, sprained ankle, tight masseter muscles, TMD (temporomandibular disorders), TMJ (temporomandibular joint disorders), 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 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.

- 1) **Evaluation:** If the patient has been evaluated to have muscle tension and restricted motion caused by an active, irritated trigger point, then proceed to Step 2.
- 2) **Spraying:**
 - A. Have the patient assume a comfortable position.
 - B. Take precautions to cover the patient's eyes if spraying near the face.
 - C. Hold the can upright. From a distance of 30 to 46 cm (12 to 18 inches), aim the stream so that it

meets the skin at an acute angle lessening the shock of impact.

- D. Direct the spray in parallel sweeps 1.5 to 2 cm (0.5 to 1 inch) apart at the rate of approximately 10 cm per second (4 inches 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.

- 3) **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.

Temporary Relief of Minor Sports Injuries: The pain of bruises, contusions, swelling and minor sprains may be controlled with Gebauer's Spray and Stretch. The amount of cooling depends on the dosage. Dosage varies with duration of application. The anesthetic effect of Gebauer's Spray and

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Stretch rarely lasts more than a few seconds to a minute. This time interval is usually sufficient to help reduce or relieve the initial trauma of the injury. Spray Gebauer's Spray and Stretch on the target area continuously for 4 to 10 seconds from a distance of 3 to 7 inches (8 to 18 cm). Spray until the skin just begins to turn white; do not frost the skin. Avoid spraying of skin beyond this state. Reapply as needed.

Pre-Injection Anesthesia: Prepare the syringe. Swab the treatment area with an antiseptic. Spray the treatment area with Gebauer's Spray and Stretch continuously for 4 to 10 seconds from a distance of 3 to 7 inches (8 to 18 cm) until the skin just turns white. Do not frost the skin/area. Avoid spraying the target area beyond this state. With the skin taut, quickly introduce the needle. Reapply as needed.

Bibliography

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Ordering Information

R_x Only.

Gebauer's Spray and Stretch is available in a 3.5 fl. Oz. (103.5 mL) Aerosol Can.

Gebauer's Spray and Stretch
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