Gebauer's Pain Ease®

Gebauer's Pain Ease® is an

Unclassified Prescription Medical Device

Gebauer's Pain Ease® is regulated in the United States by the FDA as an Unclassified Prescription Medical Device. Gebauer's Pain Ease, a topical anesthetic skin refrigerant, required submission to the FDA of documentation supporting the use of the device prior to placing the product on the market. Gebauer's Pain Ease was cleared for marketing by the US FDA on March 17, 2004 under 510(k) Number K032671. A copy of the clearance letter issued by the FDA is attached.

Gebauer's Pain Ease Mist and Medium Stream Spray were cleared for marketing with the following indications:

> A vapocoolant (skin refrigerant) intended for topical application to skin, intact mucous membranes (oral cavity, nasal passageways and the lips) and minor open wounds. Gebauer's Pain Ease controls pain associated with minor surgical procedures (such as lancing boils, incisions, drainage of small abscesses, and sutures), injections (venipuncture, IV starts, cosmetic procedures) and the temporary relief of minor sports injuries (sprains, bruising, cuts and abrasions). The Medium Stream Spray is also intended for the treatment of myofascial pain caused by trigger points, restricted motion and muscle tension.

A 510(k) is a premarketing submission made to FDA to demonstrate that the device to be marketed is as safe and effective, that is, substantially equivalent (SE), to a legally marketed device. Applicants must compare their 510(k) device to one or more similar devices currently on the U.S. market and make and support their substantial equivalency claims. The legally marketed device(s) to which equivalence is drawn is known as the "predicate" device(s). The predicate devices for Gebauer's Pain Ease are Gebauer's Spray and Stretch® and Gebauer's Ethyl Chloride®.

Applicants must submit descriptive data and, when necessary, performance data to establish that their device is SE to a predicate device. Again, the data in a 510(k) is to show comparability, that is, substantial equivalency (SE) of a new device to a predicate device. SE means that the new device is as safe and effective as the predicate device(s).

The following table is a brief description of some of the most requested test data that was used to support the 510(k) for Gebauer's Pain Ease. Please refer to the Pain Ease Technical Data Document included in this package for a more complete description of the tests and results.

Gebauer Company

The Most Trusted Name In Skin Refrigerants For Over 100 Years!®

Products Made in the U.S.A.

4444 East 153rd Street • Cleveland, Ohio 44128
1-800-321-9348

www.GebauersPainEase.com

Safety[1] & Efficacy Testing Summary

TEST[2]	STANDARD	RESULT
TOXICITY TESTING		
Cytoxicity	ISO 10993-5	Non Cytotoxic to Human HaCat keratinocyte cells
Dermal Sensitization	ISO 10993-10 (Modified Buehler Method)	Not a dermal sensitizer
Dermal Irritation	OECD Guidelines	Not a dermal irritant
Oral Irritation	ISO 10993-10	Not an irritant to mucous membranes
Acute System Toxicity	ISO 10993-11	Non-Toxic
PERFORMANCE TESTNG		
Leakage	USP<601>	Meets Requirements
Accelerated Stability	Q1A Stability Testing, ICH Guidance for Industry	Meets Requirements to assign a two year expiration period
Material Compatibility	FDA Guidance	No leachables or breakdown of packaging components
Microbial Limit	USP<61>, USP<62>	Product does not support microorganism growth and is free of specific pathogenic organisms

[1]Safety Testing was performed in accordance with FDA's Blue Book Memorandum #G95-I, entitled *"Use of International Standard ISO 10993, Biological Evaluation of Medical Devices, Part I: Evaluation of/Medical Devices."*

[2]FDA Blue Book Memorandum #G95-I identifies these as required biocompatibility tests for a surface device to be used on skin, mucous membranes and breached or compromised skin with a limited (24 hour) contact duration.

Gebauer's Pain Ease is manufactured in accordance with the FDA's good manufacturing practices and Gebauer's facility is registered with the FDA as a medical device establishment. Gebauer Company is also certified to two other internationally recognized quality system standards: ISO 9001 and ISO 13485. Additionally, Gebauer's Pain Ease is also approved for sale in Canada and the European Union.

Gebauer Company

The Most Trusted Name In Skin Refrigerants For Over 100 Years!®

Products Made in the U.S.A.

4444 East 153rd Street • Cleveland, Ohio 44128
1-800-321-9348

www.GebauersPainEase.com

Prescription Only Medical Device

The FDA has designated Gebauer's Pain Ease Mist Spray and Medium Spray as Prescription only (Rx) medical devices. This designation means that Pain Ease can be sold to and purchased by any healthcare practitioner who is licensed by the state in which they practice. Healthcare practitioners include doctors, chiropractors, physical therapists, nurses, etc. Any healthcare professional should be able to purchase prescription devices without restriction.

Gebauer's Pain Ease may be purchased by any patient who receives a prescription or "other order" from any licensed healthcare practitioner (above mentioned). An "other order" is defined as an instruction from a healthcare practitioner to use a prescription device.

To obtain additional information regarding the regulatory status of Gebauer's Pain Ease Mist Spray or Medium Stream Spray, please contact Gebauer's Director of Regulatory Affairs, Amy Paukovits, at 216-581-3030, ext. 120 or by email at Amy.Paukovits@gebauer.com.

Gebauer Company
The Most Trusted Name In Skin Refrigerants For Over 100 Years!®
Products Made in the U.S.A.

4444 East 153rd Street • Cleveland, Ohio 44128
1-800-321-9348

www.GebauersPainEase.com