

DermaFreeze™
(Ethyl Chloride)

Prescribing Information

DermaFreeze™ is a colorless, flammable, volatile liquid. It will vaporize at room temperature when applied from its metal container.

Indications and Usage

DermaFreeze™ is a vapocoolant intended for topical application for the control of pain associated with minor surgical procedures (such as lancing boils, or incision and drainage of small abscesses), injections, and contusions.

Precautions

Inhalation of **DermaFreeze™** should be avoided as it may produce narcotic and general anesthetic effects, and may produce deep anesthesia or fatal coma with respiratory or cardiac arrest. **DermaFreeze™** is **FLAMMABLE** and should never be used in the presence of an open flame, or electrical cautery equipment. When used to produce local freezing of tissues, adjacent skin areas should be protected by application of petrolatum. The thawing process may be painful and freezing may lower local resistance to infection and delay healing.

Adverse Reactions

Cutaneous sensitization may occur, but appears to be extremely rare. Freezing can occasionally alter pigmentation.

Contraindications

DermaFreeze™ is contraindicated in individuals with a history of hypersensitivity to Ethyl Chloride. This product should not be used on patients having vascular impairment of the extremities.

Warnings

For external use only.

Skin absorption can occur; no cases of chronic poisoning have been reported.

DermaFreeze™ is known as a liver and kidney toxin; long term exposure may cause liver or kidney damage.

This product contains a chemical known to the State of California to cause cancer.

Keep out of reach of children!

Administration by or to a pregnant or nursing woman is not recommended.

Dosage and Administration

To apply **DermaFreeze™** from its metal container, hold the container approximately 3 inches (7.5 cm) from the area of the skin to be treated. Point the actuator button located on the top of the container at the area to be treated. Depress the actuator button for the length of time necessary to achieve the desired

I. Topical Anesthesia in Minor Surgery

The operative site should be deansed with a suitable antiseptic. Apply petrolatum to protect the adjacent area. Spray **DermaFreeze™** for a few seconds to the point of frost formation, when the skin becomes white. Avoid spraying of skin beyond this state. The anesthetic action of **DermaFreeze™** rarely lasts more than a few seconds to a minute. Quickly swab the operative site with antiseptic and promptly make incision.

II. Temporary Relief of Minor Sports Injuries

The pain caused by bruises, contusions, swelling, and minor sprains may be controlled with **DermaFreeze™**. Spray affected area for a few seconds until the tissue begins to frost and turn white. Avoid spraying the skin beyond this state. Use as you would ice. The amount of cooling will depend on the dosage. The smallest dose needed to produce the desired effect should be used. Determine the extent of injury (fracture, sprain, etc.). The anesthetic effect of **DermaFreeze™** 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.

III. Pre-Injection Anesthesia

Prepare a syringe and have it ready. Spray skin with **DermaFreeze™** from a distance of about 3 inches (7.5 cm) continuously for 2 to 4 seconds. **Do not frost the skin.** Swab the skin with alcohol and quickly introduce the needle with the skin taut.

Caution: Federal law (USA) restricts this product to sale by or on the order of a physician or other practitioner licensed by state law to use or order use of this product.

How Supplied: Made for and distributed exclusively by Medix Pharmaceuticals Americas Inc., Greenbelt, MD 20770 under license from Rhealm Pharmaceutical, Inc.

3.6 Fl. Oz. (106.5 mL) can

Storage: Contents under pressure. Do not puncture or incinerate. Do not use near open flame or expose to heat. Store in a cool place. Do not store above 120°F. Do not store on or near high frequency ultrasound equipment.

U.S. Patent: 5941243

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