

INSTRUCTIONS FOR USE COOLJECT™ TOPICAL ANESTHETIC CANISTER

CAUTION: Rederal (USA) law restricts this device to sale by or on the order of a licensed physician or properly licensed practitioner.

DEVICE DESCRIPTION: CoolJect Topical Anesthetic Canister is a vapocoolant (skin refrigerants) canister with a nozzle intended for instant topical anesthetic.

INDICATIONS FOR USE: The CoolJect Topical Anesthetic Canister is intended for topical application to skin, intact mucous membrane (oral cavity, nasal passageways, lips) and minor open wounds. The CoolJect Topical Anesthetic is used to target and minimize cooling area for lessening pain associated with injections (venipuncture, IV starts, cosmetic procedures), minor surgical procedures (such as lancing boils, incision, drainage of small abscesses and sutures) and the temporary relief of minor sports injuries (sprains, bruising, cuts, and abrasions).

PRECAUTIONS:

- Do not spray into the eyes. Cover eyes with a gauze to avoid unintentional misting close to the eyes when used within 4 inches of eyes, nostrils or mouth and to close eyes and mouth when within 4 inches.
- Do not spray onto poor circulation (I.e. Diabetic) or insensitive skin.
- Do not spray on large areas of damaged skin, puncture wounds or animal bites or serious wounds.
- Do not use on genital mucous membrane. Apply only to intact mucous membrane.
- The freezing and thawing process may be painful and freezing may lower local resistance to infection and delay healing.
- Over application of the same area may cause frostbite and/or alter skin or mucosa pigmentation. Cover areas that are not intended to be affected with the application of petroleum jelly.
- Discontinue use if rash develops.
- Thin skin will require less misting than thicker skin or mucosa (thickness depends on fat storage and blood vessel and keratin).

ADVERSE REACTIONS: Freezing can occasionally alter skin pigmentation.

CONTRAINDICATION: 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. Contents under pressure. For use on minor open wounds only. For use on intact mucous membranes only.

CONTENTS: 1,1,1,3,3-Pentafluoropropane and 1,1,1,2-Tetrafluoroethane

STORAGE: Do not puncture or incinerate canister. Do not expose to heat or store in temperatures above 120°F (50°C).

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

KEEP OUT OF REACH OF CHILDREN

INSTRUCTIONS: The CoolJect Topical Anesthetic Canister can only be used with the CoolJect Accessory Nozzle which is sold separately.

DISCARD AFTER USE: Follow local, state and government requirements for disposal of aerosol containers.

HOW SUPPLIED:

VM02000-03 CoolJect[™] Topical Anesthetic Canister, 3 pack Note: each canister holds 2.0 wt. oz. (60ml) P/N VM02000-00



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Manufactured for:

VapoCoolShot Inc.

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