



BIOFREEZE[®]

COLD THERAPY PAIN RELIEF




**Available in over
60 countries &
26 languages**

(*) Ref: 2010 Market Study by the Allegheny Marketing Group- USA

The innovative product in gel and spray form
relieves muscle and joint pain based on the beneficial
properties of Cryotherapy - The Cold Method®



Pain relief that works® for:

- Muscle Aches and Spasms
- Pain in Waist, Back, Shoulder, Neck, Knee, Hip, Elbow and Ankle
- Arthritis and Tendinitis Pain
- Sore Muscles
- Pain from Injury during Sports and Exercise
- Painful Sprains, Strains, Bumps, Pulls and Bruises

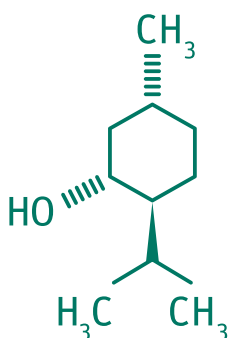
Ingredients

Isopropyl Alcohol, Benthol & Herbal Extract (Ilex Paraguariensis).
 Camphor, Carbomer, Glycerine, Methylparaben, Propylene Glycol,
 Silicon Dioxide, Water, Triethanolamine, FD&C yellow #5, FD&C blue # 1.

Biofreeze® Pain Reliever delivers cold relief

Clinically proven Cryotherapy made convenient

It has long been established that cold therapy, or “cryotherapy”, decreases pain and reduces inflammation. Biofreeze Pain Reliever is a topical analgesic that delivers the therapeutic benefits of cryotherapy in an effective, easy-to-use formula, through USP*- grade ingredients for proven analgesic effectiveness¹. Clinical evidence** attests to the effectiveness of Biofreeze Pain Reliever and accounts for its standing as the #1 clinically used and recommended topical analgesic by hands on healthcare professionals in USA.



(*) USP: An indicator of quality

The United States Pharmacopeia (USP) sets standards to ensure the quality of medications, food ingredients, and healthcare products. Biofreeze Pain Reliever is formulated with USP-grade menthol, camphor, isopropyl alcohol, and water. Our choice of USP-grade ingredients distinguishes Biofreeze Pain Reliever from other topical analgesics and is testimony to our commitment to quality.

(**) Bishop B et al. 2011. Effects of Biofreeze vs. ice on acute, non-complicated neck pain (Abstract) *Clinical Chiropractic* 14(4):153-54 • Brosky JA et al. 2012. Effect of 3.5% menthol gel on knee pain and functioning in patients with knee osteoarthritis (Abstract) *J Orthop Sports Phys Ther* 42(1):A106-7 • Johar et al. 2012. A comparison of topical menthol to ice on pain, evoked tetanic and voluntary force during delayed onset muscle soreness. *Int J Sports Phys Ther.* 7(3):314-22. • Olive JL et al. 2010. Vascular conductance is reduced after menthol or cold application *Clin J Sport Med* 20(5):372-6. • Topp R et al. 2011. Effect of topical menthol on ipsilateral and contralateral superficial blood flow following a bout of maximum voluntary muscle contraction. *Int J Sports Phys Ther* 6(2):83-91 • Topp R et al. 2011. Comparison of the effects of ice and 3.5% menthol gel on blood flow and muscle strength of the lower arm *J Sport Rehabil* 20:355-366 • Zhang J et al. 2008. Effects of Biofreeze and chiropractic adjustments on acute low back pain: a pilot study *J Chiropractic Med* 7:59-65

Mechanism of action

The counter - irritant / Gate Control Theory

Traditional thinking is that the pain-relieving mechanism of action of menthol, an ingredient in Biofreeze Pain Reliever, results from a counter-irritant effect. Simply put, a counter-irritant has an effect of overriding noxious pain signals traveling to the brain through a process modulated between pain-transmitting and non-pain transmitting neurons. This process, known as “gate control” or “gating,” was first described by Melzack and Wall.²

Gate control theory is based on the understanding that pain is transmitted by two kinds of afferent nerve fibers. One is the larger myelinated A-delta fiber, which carries quick, intense-pain messages. The other is the smaller, unmyelinated “C” fiber, which transmits throbbing, chronic pain. A third type of nerve fiber, called A-beta, is “nonnociceptive,” meaning it does not transmit pain stimuli. The gate control theory asserts that signals transmitted by the A-delta and C pain fibers can be thwarted by the activation/stimulation of the nonnociceptive A-beta fibers and thus inhibit an individual’s perception of pain.

More recently, researchers have discovered that menthol further stimulates the TRPM8 cold receptors. Even though it has long been accepted that cooling and cold can induce analgesia, the mechanism has been poorly understood. Now, as scientists have continued to isolate these specific heat-sensitive transient receptor potential (TRP) channels within our sensory neurons we are now able to have a much better understanding of the body’s cutaneous temperature detection. With the isolation and further study of these specific TRPM8 receptors there is stronger evidence supporting the benefits achieved with the cooling effect of menthol in functioning as a topical analgesic while activating these receptors and the resulting consequent pain relief.



Like ice, only better

The pain - relieving power of menthol

Ice is the time-honored means of effectively delivering cryotherapy, but ice does have disadvantages. It can cause muscle stiffness, skin irritation, temporary pain and numbness, and it generally requires the patient to remain stationary.

Biofreeze Pain Reliever has been shown to be as effective as ice without the disadvantages.³ Like ice, Biofreeze Pain Reliever reduces pain and inflammation. One study determined that blood flow decreased in the radial artery five minutes after Biofreeze Pain Reliever was applied to the forearm; 20 minutes were required for ice to induce the same result. While Biofreeze reduced blood flow much quicker than ice, the reduction lasted longer in the ice condition. This quick reduction may be a great benefit in the very acute stages of injury, but more research is needed.⁴ In another study, patients with bilateral neck pain preferred, by an 8-to-1 margin, treatment with Biofreeze Pain Reliever to treatment with ice, and nine out of ten patients felt that Biofreeze Pain Reliever was twice as effective and that relief lasted longer, compared to ice.⁵

The short-term pain relief provided by Biofreeze Pain Reliever facilitates ease of movement, which can promote faster, long-term healing and recovery. It may be used to control pain during therapy and by patients and clients, at home or on-the-go. When used before exercise and/or therapy, Biofreeze Pain Reliever promotes pain-free movement. After activity, Biofreeze Pain Reliever soothes sore muscles and joints.⁶

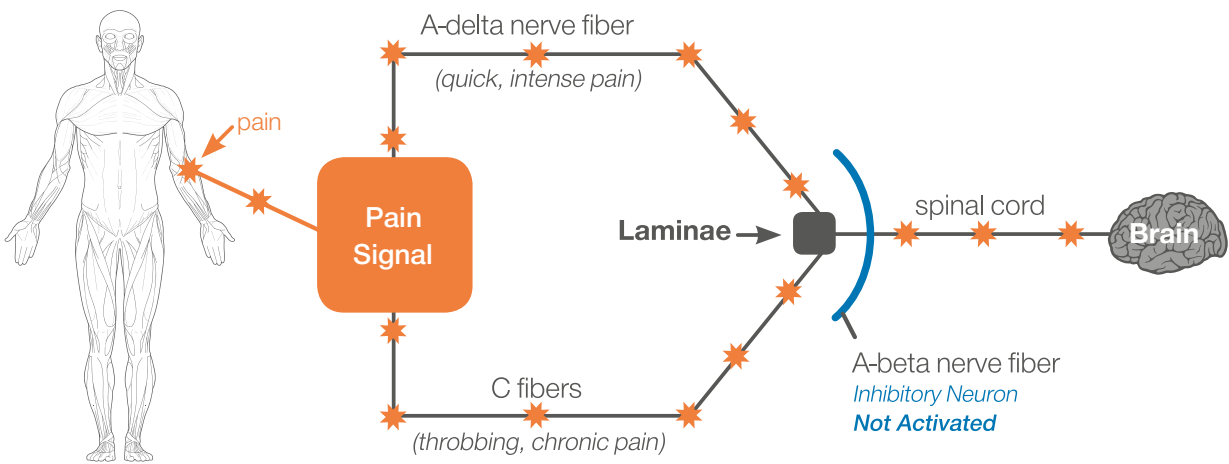
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The Melzack-Wall Pain Gate

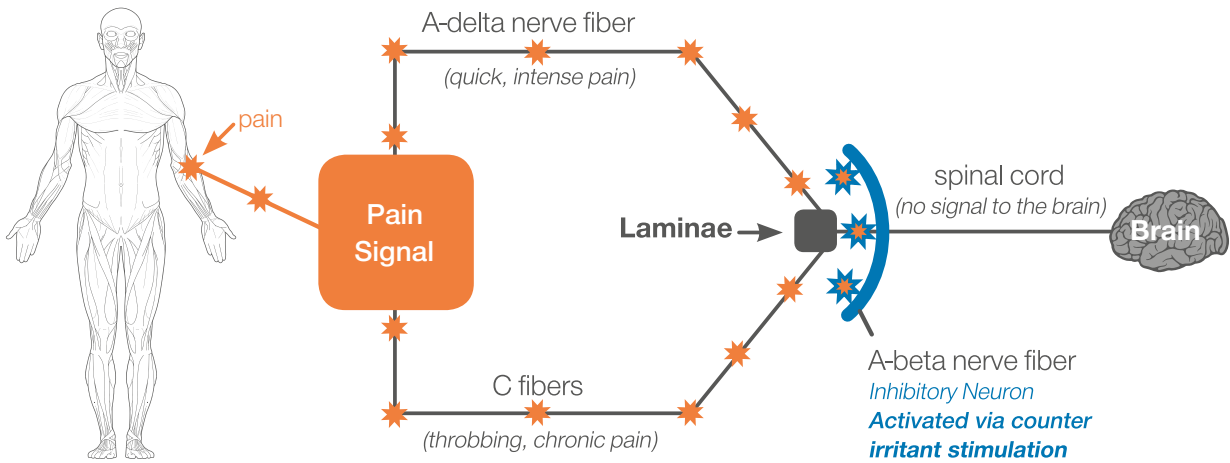
The brain's perception of pain depends on the interaction—within the laminae of the spinal cord—of C and A-delta nerve fibers (pain-transmitting) with A-beta nerve fibers (non-pain-transmitting). Stimulating the A-beta nerve fibers ultimately activates the inhibitory interneuron and “closes the gate” to pain.

Pain is Perceived



Pain is NOT Perceived

Apply Biofreeze to painful area



Cold therapy for every setting

A natural, targeted route to relief

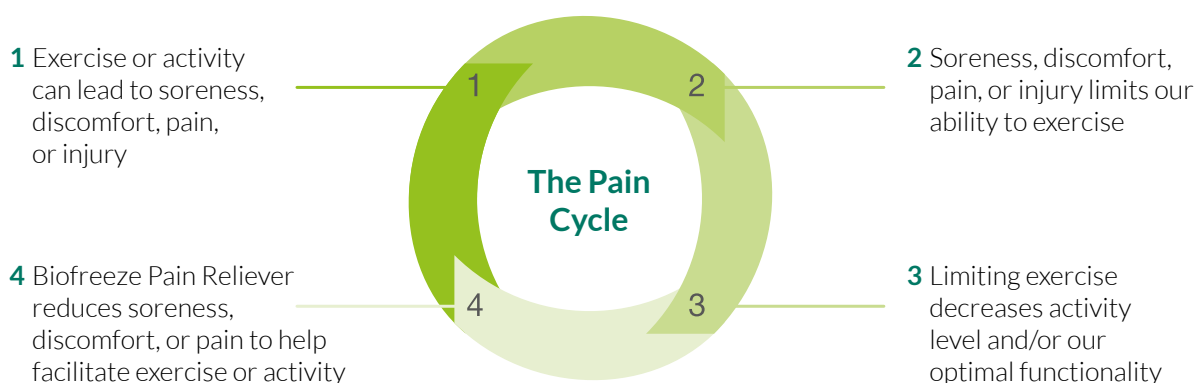
Patient care: Apply Biofreeze Pain Reliever before, during, and after treatment or therapy to further enhance your level of hands-on professional care. Likewise, recommend Biofreeze Pain Reliever as part of your patient's or client's in-home treatment plan. Such as:

- adjunctive modality with therapies
- Graston Technique®*
- Orthotics
- Spinal Decompression

Pain management: Patients and clients heal more slowly when pain hinders their ability to perform rehabilitation therapies and exercises. Biofreeze Pain Reliever, massaged into sore muscles and joints, can make it easier for your patients and clients to fully participate in treatment sessions. By delivering fast pain relief, Biofreeze Pain Reliever can aid in your treatment of injuries and chronic problems that traditionally call for ice and breathable wraps.

(*) Graston Technique is a registered trademark of the Graston Corporation

How Biofreeze Pain Reliever manages the Pain Cycle



Exercise and training: Biofreeze Pain Reliever can aid exercise and training - and ease the sometimes uncomfortable after effects - by relieving pain to increase range of motion. Apply Biofreeze Pain Reliever before exercise to take soreness out of muscles and/or after cool-down routines to minimize next-day aches and pains. For sore muscles, apply directly to the area before and/or after exercise. Combine with massage, as needed.

Dosage - How to use

Adults: Apply to the affected area up to 4 times a day.

Children: Ask for medical advice before use.

Pregnancy: Ask for medical advice before use

Evidence encourages the use of topical analgesics

The trend is toward targeted relief

Today, throughout the pain management community, the shift is toward the use of topical analgesics and away from systemic pain relievers. Fueling this trend is evidence-based research linking currently available systemic pain relievers to adverse events.⁷ NSAIDs, COX-2 inhibitors, and opioids can affect the gastrointestinal tract, heart, kidneys, and other organs, as well as cognition.

Conversely, topical analgesics, such as Biofreeze Pain Reliever, deliver targeted pain relief with low levels of systemic absorption and therefore less risk for systemic toxicity and/or drug interaction. Pain-management clinicians are encouraged to consider and recommend topical analgesics as effective, safer alternatives to systemic medications.⁷

One effective pain reliever in three different formats



- **Roll-On:** Roller application allows effective delivery of Biofreeze gel to smaller muscles and joints throughout the body. The massaging action of the roller ball can be used to stimulate trigger points in the affected area.
- **Spray:** Biofreeze Cryospray® permits easy, effective application without direct body contact, helping patients at home gain access to hard-to-reach body areas such as the back.
- **Gel:** Gel-dispensing tube is particularly well-suited for hands-on massage applications (particularly larger muscles and joints).

ORIGINAL RESEARCH

Vascular Conductance is Reduced After Menthol or Cold Application

Jennifer L. Olive, PhD,* Brandon Hollis, MS,† Elizabeth Mattson, MS,† and Robert Topp, PhD‡

Objective: To compare the effects of eucalyptus oil menthol (0.5%) ointment and cold application on blood flow in the forearm.
Design: Prospective, cross-sectional design.
Settings: University research laboratory.
Participants: Twelve (7 men and 5 women) college-aged students.
Intervention: Each participant had blood flow measured in the brachial artery for 5 minutes before and 10 minutes after menthol ointment or cold application to the forearm.

Main Outcome Measures: Blood velocity, arterial diameter size, and blood pressure were measured during using ointment, and vascular conductance was calculated based on these measures and used to describe both blood flow.

Results: We observed a significant reduction (35%, $P = 0.006$) in vascular conductance within 60 seconds of menthol and cold application to the forearm. Vascular conductance remained significantly reduced for 10 minutes by approximately 19% after both menthol and cold application ($P < 0.001$, $P < 0.001$). There was no significant difference between conditions ($P = 0.085$, $P = 0.845$).

Conclusion: The application of a 1.7% menthol ointment significantly reduces vascular conductance in the brachial artery within 60 seconds of application, and this effect is maintained for at least 10 minutes after application. The overall decline in conductance in vascular tissue resulted in a decrease in blood flow.

Key Words: blood flow, menthol, vascular conductance, Doppler ultrasound, cryotherapy
(*J Sport Med 2012;20(3):375-376*)

INTRODUCTION

Athletic trainers and physical therapists use cryotherapy (the application of ice for therapeutic purposes) to reduce inflammation and pain as a means to reduce inflammation and pain in athletes performance or injuries. Cryotherapy of athletes performance or injuries by reducing inflammation reduces inflammation by reducing blood flow to the injured tissue. This is achieved by vasoconstriction of the blood vessels, which in turn reduces the metabolic demand of injured tissues.^{1,2} In a meta-analysis, cold application significantly reduced blood flow, cold application significantly reduced intramuscular blood flow,^{3,4} and intramuscular blood flow has been shown to be related to pain by inhibiting nerve conduction.⁵ It has been documented over the years, it has been documented that responses are multifactorial but are likely to involve sensory neurons, which affect the nociceptive signaling.^{6,7}

Efficacy of Cold Gel for Soft Tissue Injuries
A Prospective Randomized Double-Blinded Trial

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Background: The use of cold treatment to limit edema, decrease pain, and induce affective muscle relaxation in soft tissue injuries is widespread in sports medicine.
Purpose: To compare the efficacy of a novel cold gel with that of a placebo gel in patients with a soft tissue injury.
Study Design: Prospective randomized double-blind controlled trial.
Methods: Seventy-four patients with sports-related soft tissue injury were randomly assigned to active cold gel (Bio Freeze) or placebo gel group. The gel was applied four times daily on the site for 14 days. Clinical assessment was made after 7, 14, and 28 days with use of visual analog scale (VAS) and patient self-reported pain ratings.
Results: Pain scores decreased from 58 to 30 during the first week, to 14 by the second, and to 7 by the end of study in the cold gel group. In the placebo group, pain scores decreased from 62 to 45, 20, and 13, respectively (significant difference) during the first week, to 10 by the second, and to 5 by the end of study in the cold gel group.
Conclusions: Cold gel therapy provided an effective and safe treatment for sports-related soft tissue injuries.

Effects of Biofreeze vs. Ice on Acute, Non-Complicated Neck Pain

Barton Bishop, Jay Greenstein, Bob Topp

Background: Cryotherapy has long been used by physical therapists and chiropractors in the management of acute pain and more recently it has been shown to effectively increase blood flow and help to control pain; however, there is limited research to determine which form of cryotherapy works better on individual patients.
Methods: Fifty-one males and females between the ages of 19 and 65 (37 +/- 11.2 years) with bilateral non-radicular, acute neck pain (myalgia) were given both ice and the topical Biofreeze® on each side of the neck. The patients had no history of surgery in the neck in the last year. The study was a randomized, controlled trial.

The Biofreeze® was on the neck for 15 minutes. The VAS for each side of the neck was recorded. In addition, the patients were asked to rate their pain level and to pick whether they preferred the ice or the Biofreeze® for a longer lasting effect.

reference, patients preferred the Biofreeze® (point Likert scale was 4.20 for ice and 5.00 for Biofreeze®). The 5 point Likert scale was 4.47 for ice and 5.00 for Biofreeze®. This indicates a significant reduction in pain on the neck in the last year.

increased pain levels; however, Biofreeze® was preferred by 9 out of 10 times. This indicates that Biofreeze® is a more effective cryotherapy modality than ice. Conservative care specialists should consider Biofreeze® as the primary method of treatment for acute neck pain.

To determine whether this short term treatment in outcomes, improved patient satisfaction, and reduced pain on the neck in the last year.

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