



This topical pain medication was recently reformulated and improved by pharmacists who specialize in pain management. In addition, natural ingredients have been added to the formula for a better, more soothing smell. Scientific studies have shown that both the natural and pharmaceutical ingredients used in this product significantly reduce pain and inflammation.<sup>i</sup> A combination of ingredients with analgesics and anesthetic properties are used in a unique way to maximize its pain relieving effects. This offers long lasting relief for a variety of pain conditions. New Terocin is manufactured in accordance with FDA regulations by an FDA approved manufacturer.

**Active Ingredients:** Methyl Salicylate 25%  
Capsaicin 0.025%  
Menthol 10%



**Uses:** This formulation can be used to assist patients in the treatment of mild to moderate acute or chronic aches or pain. Muscle or joint pain can be due to musculoligamentous strains, simple backache, tendonitis, osteoarthritis, rheumatoid arthritis, peripheral neuropathies such as diabetic neuropathy or post herpetic neuralgia, and other complex regional pains. It can also be used to help with certain types of headaches but use with caution when applying in order to avoid eye contact.<sup>ii</sup> If consulted by your physician, it may be used for other conditions as well.

**Directions:** Wash and dry the affected area. Shake bottle well before each use and gently rub over area of pain thoroughly. The usual dose depends on the severity and area of pain, but generally 5 grams or about the size of a quarter should be used. It is not recommended to use this medication more than four times a day. Do not apply near the eyes, mouth, nose, or genitals and immediately wash your hands well after use. If treating the hands, wait at least 30 minutes after applying the medication to wash your hands. Pain relief may take two to three weeks to see noticeable effect. One (120 mL) to two bottles (240 mL) should last approximately one month depending on the size of the affected area.

#### **Mechanism of Action:**

*Methyl salicylate*, also known as wintergreen oil, is a natural product from many plant species. It is topically used to cause dilation of the capillaries thereby increasing blood flow to the area.

*Capsaicin* is an active component from chili peppers that produces a burning sensation on the skin. The true mechanism is not fully understood, but it is believed to be a neuropeptide-active agent that decreases and depletes the synthesis, storage, transport, and release of substance P. Substance P is thought to be the principal chemical mediator of pain impulses from the periphery to the central nervous system. It is also hypothesized that substance P is released into joint tissues where it activates an inflammatory response. When capsaicin depletes substance P in the nerve endings, the local pain impulses can no longer be transmitted to the brain.

*Menthol* has some local anesthetic and counterirritant qualities and also acts as a weak kappa opioid receptor agonist making it an analgesic as well. Its ability to chemically trigger the cold-sensitive TRPM8 receptors in the skin is responsible for its cooling sensation when applied to the skin. Lastly, it enhances the efficacy of other topical applications by increasing penetration via vasodilation.

**Benefits:** The use of this topical medication, New Terocin, over other oral options for pain relief can benefit patients in many different ways. Conventional therapies using opioids (hydrocodone, hydromorphone, morphine, oxycodone) can cause systemic adverse effects such as constipation, drowsiness, dizziness, lightheadedness, nausea, vomiting, sedation, and/or confusion. NSAIDs (ibuprofen, naproxen) can increase cardiovascular risk, decrease platelet aggregation, and cause gastrointestinal bleeding or ulcers. Other classes of medications such as antidepressants (nortriptyline, duloxetine) or anticonvulsants (gabapentin) also come with its costs and side effects. New Terocin acts only locally since it penetrates the skin and not into the bloodstream. In addition, patients can have one or multiple disease states including renal or hepatic dysfunction which can prevent them from taking ibuprofen (Advil) or acetaminophen (Tylenol) respectively. More importantly, New Terocin gives physicians an option to provide effective pain relief treatment while avoiding the addictive properties of conventional oral medications.

**Product Information and Data:** The ingredients used in this product have been proven to reduce inflammation and pain.<sup>iii</sup> Pharmacists that have been in the field of pain management for many years used research from all parts of the world to carefully formulate this lotion in order to maximize its pain relieving properties.<sup>iv</sup> Skin penetrating mixtures have also been added to enhance rapid absorption of the active ingredients through the skin to allow deeper penetration into the muscles, joints, and nerves. The use of these pharmaceutical and natural components provides more pain relief and makes New Terocin superior to other topical pain medications. These ingredients comply with The Chronic Pain Medical Treatment Guidelines and the ACOEM guidelines for pain management.<sup>v</sup> Page 111 of the Chronic Pain Medical Treatment Guidelines concludes that topical analgesics are “primarily recommended for neuropathic pain when trials of antidepressants and anticonvulsants have failed (Namaka, 2004).” In addition to this, “these agents are applied locally to painful areas with advantages that include lack of systemic side effects, absence of drug interactions, and no need to titrate (Colombo, 2006).” Specifically on page 105, topical methyl salicylate is significantly better than placebo in chronic pain (Mason-BMJ, 2004). Under the topical capsaicin section (page 28-29), the use of capsaicin is “recommended only as an option in patients who have not responded or are intolerant to other treatments,” furthermore “there are positive randomized studies with capsaicin cream in patients with osteoarthritis, fibromyalgia, and chronic non-specific back pain.” This product is therefore “recognized as safe and effective” because it meets all conditions of the CFR.<sup>vi</sup> New Terocin complies with The Chronic Pain Medical Treatment Guidelines and the ACOEM guidelines for a variety of pains mentioned above.<sup>vii</sup>

**Adverse Reactions:** Even though adverse reactions are rare, a very small percentage of patients experience an unpleasant burning sensation, redness, warmth, or stinging. It is advisable to apply a small amount on the forearm prior to first use. If any of these effects persists or worsens, contact your physician or pharmacist immediately. This medication is not absorbed systemically but if any serious side effects (i.e. rash, itching/swelling, severe dizziness) are experienced, discontinue use immediately and contact your pharmacist or physician. This is not a complete list of all side effects that may occur. You may report side effects to the FDA at 800-FDA-1088 or at <http://www.fda.gov/medwatch>.

#### **Warnings:**

- **Only for external use**
- **Do not use:** on open wounds, cuts, damaged or infected skin as well as in the eyes, mouth, genitals, or any other mucous membranes.
- **Consult your physician:** if pain persist or worsens or if using any other topical pain products.
- Call poison control if swallowed. If contact with eyes occurs, rinse eyes thoroughly with cold water.
- **Keep away from children.** Consult physician for children under 12.
- Store in a dry, cool place
- Do not use if pregnant

**In Case of Ingestion or Overdose,** get medical help or contact a Poison Control Center (800-222-1222) right away.

**Inactive Ingredients:** Water (Aqua), Cetyl Alcohol, Stearic Acid, Glyceryl Stearate, PEG-100 Stearate, Propylene Glycol, Dimethyl Sulfone, Lavandula Angustifolia (Lavender) Oil, Lidocaine, Aloe Barbadosensis Leaf Extract, Borago Officinalis Seed Oil, Boswellia Serrata Extract, Xanthan Gum, Triethanolamine, Methylparaben, Propylparaben, DMDM Hydantoin, Iodopropynyl Butylcarbamate

<sup>i</sup> Dunteman E. Targeted peripheral analgesics in Chronic Pain Syndromes. Practical Pain Management 2005; July/August: 14-25

<sup>ii</sup> Jones M. Chronic neuropathic pain: Pharmacologic interventions in the new millennium. A theory of efficacy. International J Pharmaceutical Compounding. 2004(1):6-15.

<sup>iii</sup> Higashi Y, Kiuchi T, Furuta K. Efficacy and safety profile of a topical methyl salicylate and menthol patch in adult patients with mild to moderate muscle strain: a randomized, double-blind, parallel-group, placebo-controlled, multicenter study. Clin Ther 2010;32(1):34-43.

<sup>iv</sup> Baron R, Mahn F. Types of topical treatment for peripheral neuropathic pain: Mechanism of action and indications. Schmerz 2010;24(4):317-25.

<sup>v</sup> ACOEM. *Occupational Medicine Practice Guidelines*, 2nd Edition. American College of Occupational and Environmental Medicine, 25 Northwest Point Blvd., Suite 700, Elk Grove Village, Illinois, 60007-1030 ([www.acoem.org](http://www.acoem.org)). 2004:116.

<sup>vi</sup> CFR – Code of Federal Regulations. Food and Drug Administration. Chapter 1: Part 346. Revised April 1, 2010.

<sup>vii</sup> Chronic Pain Medical Treatment Guidelines, Medical Treatment Utilization Schedule (MTUS). Effective July 18, 2009.

Topical Pain  
Relief Lotion



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NDC: 50488-1129-1 Size: 120 mL