

TEROCIN- lidocaine, menthol patch
medsource pharmaceuticals

Disclaimer: Most OTC drugs are not reviewed and approved by FDA, however they may be marketed if they comply with applicable regulations and policies. FDA has not evaluated whether this product complies.

Terocin Patch

Active ingredient

Menthol 4%

Lidocaine 4%

Purpose

Topical Analgesic

Uses:

For the temporarily relief of minor aches and muscle pains associated with arthritis, simple backache, strains, muscle soreness and stiffness.

Warnings:

1. Only for external use. Use only as directed or by a health professional.
2. **Do not use:** on open wounds, cuts, damaged or infected skin as well as in the eyes, mouth, genitals, or any other mucous membranes.
3. Do not cover with bandage.
4. **Consult your physician:** if pregnant or pain persists or worsens.

Keep out of reach of children.

Consult physician for children under 12.

Directions:

Adults and childred 12 years and over: Apply patch to affected area 1 to 2 times daily or as directed.

Instructions for use:

1. Clean and dry the affected area
2. Open pouch and remove one patch
3. Remove any protective film and apply directly to affected area of pain
4. Wash hands with soap and water after applying patch
5. Reseal pouch containing unused patches after each use

Other Ingredients:

Water, Glycerin, Sodium Polyacrylate, Polysorbate 80, Citrus Medica Limonum (Lemon) Peel Oil, Aloe Barbadesis Leaf (Aloe Vera Gel) Juice, EDTA Disodium salt, Diazolidinyl Urea, Methylparaben, Iodopronyl Butylcarbamate, Propylparaben.

1. Manufactured for : Alexso Inc.
2317 Cotner Avenue

Los Angeles, CA 90064

Store in a dry, cool place

For Comments or Questions, call 888-495-6078

Patent Pending

Package Insert

This topical pain relief patch was recently reformulated by pharmacists who specialize in pain management. Natural ingredients have been added to these patches for a better, more refreshing smell. Scientific studies have shown that both ingredients used in this product significantly reduce pain and inflammation.ⁱ A combination of ingredients with analgesics and anesthetic properties are used in a unique way to maximize its pain relieving effects and to aid in addition to other therapies. This offers long lasting relief for a variety of pain conditions. Terocin Patch is manufactured in accordance with FDA regulations by an FDA approved manufacturer.

Active Ingredients:

Menthol 4%

Lidocaine 4%

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.ⁱⁱ If consulted by your physician, it may be used for other conditions as well.

Directions:

1. Adults and children 12 years and over: Apply patch to affected area 1 to 2 times daily or as directed.
2. Instructions for Use:
 1. Clean and dry the affected area
 2. Open pouch and remove one patch
 3. Remove any protective film and apply directly to affected area of pain
 4. Wash hands with soap and water after applying patch
 5. Reseal pouch containing unused patches after each use
 6. Pain relief varies from patient to patient; may need to use a few times to see benefit.

Mechanism of Action:

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.

Lidocaine is a common local anesthetic that relieves itching, burning, and pain. Topically, it blocks both initiation and conduction of nerve impulses by decreasing ionic flux through the neuronal membrane. Since it penetrates the skin, it creates an anesthetic effect by not just preventing pain signals from propagating to the brain but by stopping them before they begin.

Benefits: The use of this topical medication, Terocin Patch, 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. Terocin Patch 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, this patch gives physicians an option to provide effective pain relief treatment while avoiding the addictive properties of conventional oral medications. It can also be supplemented with other topical pain lotions. In addition, it avoids messy application and reduces risk of getting ingredients in eyes or other mucous membranes.

Product Information and Data: 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 patch in order to maximize its pain relieving properties.ⁱⁱⁱ 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. Lidocaine patches for therapy of neuropathic and non-neuropathic pain was concluded “to be an effective and safe option for add-on therapy” (Nervenarzt, 2010) in a clinical case series using 87 patients.^{iv} Another study in 2010 concluded that a single 8 hour application of a combination patch of menthol provided significant pain relief associated with mild to moderate strains when compared to a placebo patch.^v The use of these pharmaceutical and natural components provides more pain relief and makes the patch a new way to address pain. These ingredients comply with The Chronic Pain Medical Treatment Guidelines and the ACOEM guidelines for pain management.^{vi} 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).” This product is “recognized as safe and effective” because it meets all conditions of the CFR.^{vii} Terocin Patch complies with The Chronic Pain Medical Treatment Guidelines and the ACOEM guidelines for a variety of pains mentioned above.^{viii}

Adverse Reactions: Even though adverse reactions are rare, a very small percentage of patients experience an unpleasant burning sensation, redness, warmth, or stinging. Please be aware of any unpleasant side effects as described. 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:

1. **Only for external use only.** Use only as directed or by a health professional.
2. **Do not use:** on open wounds, cuts, damaged or infected skin as well as in the eyes, mouth, genitals, or any other mucus membranes.
3. Do not cover with bandage.
4. **Keep away from children.** Consult physician for children under 12 years.
5. **Consult your physician:** if pregnant or if pain persists or worsens
6. **Consult your physician:** if pain persist or worsens or if using any other topical pain products.
7. Store in a dry, cool place

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

Inactive Ingredients: Water, Glycerine, Sodium Polyacrylate, Polysorbate 80, Citrus Medica Limonum (Lemon) Peel Oil, Aloe Barbadesis Leaf (Aloe Vera Gel) Juice, EDTA Disodium salt, Diazolidinyl Urea, Methylparaben, Iodopropynyl Butylcabamate, Propylparaben.

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

ⁱⁱ Jones M. Chronic neuropathic pain: Pharmacologic interventions in the new millennium. A theory of

efficacy. International J Pharmaceutical Compounding. 2004(1):6-15.

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

iv Kern KU, Kohl M, Kiefer RT. Lidocaine patch for therapy of neuropathic and non-neuropathic pain. A clinical case series of 87 patients. Nervenarzt 2010 Dec;81(12): 1490-7.

v 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. Clinical Therapeutics. 2010 Jan;32(1): 34-43.

vi 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.). 2004:116.

vii CFR – Code of Federal Regulations. Food and Drug Administration. Chapter 1: Part 346. Revised April 1, 2010.

viii Chronic Pain Medical Treatment Guidelines, Medical Treatment Utilization Schedule (MTUS). Effective July 18, 2009.

Topical Pain

Relief Patch

Alexso inc.

Package/Label Principal Display Panel



TEROCIN

lidocaine, menthol patch

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:45865-759 (NDC:50488-1001)
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
LIDOCAINE (UNII: 98PI200987) (LIDOCAINE - UNII:98PI200987)	LIDOCAINE	600 mg
MENTHOL, UNSPECIFIED FORM (UNII: L7T10EIP3A) (MENTHOL, UNSPECIFIED FORM - UNII:L7T10EIP3A)	MENTHOL, UNSPECIFIED FORM	600 mg

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
GLYCERIN (UNII: PDC6A3C0OX)	
SODIUM POLYACRYLATE (250000 MW) (UNII: 05115JN12J)	
POLYSORBATE 80 (UNII: 6OZP39ZG8H)	
LEMON OIL (UNII: I9GRO824LL)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	
DIAZOLIDINYL UREA (UNII: H5RIZ3MPW4)	
METHYLPARABEN (UNII: A2I8C7HI9T)	
IODOPROPYNYL BUTYLCARBAMATE (UNII: 603P14DHEB)	
PROPYLPARABEN (UNII: Z8IX2SC1OH)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:45865-759-01	2 in 1 BOX	06/01/2018	
1		5 in 1 POUCH; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part348	05/01/2013	

Labeler - medsource pharmaceuticals (833685915)

Establishment

Name	Address	ID/FEI	Business Operations
medsource pharmaceuticals		833685915	repack(45865-759)

Revised: 12/2018

medsource pharmaceuticals