LM PLUS RELIEF- lidocaine and menthol patch
ARI BRANDS, LLC

Disclaimer: This drug has not been found by FDA to be safe and effective, and this labeling has not been approved by FDA. For further information about unapproved drugs, click here.

LM Plus Relief Patch

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What is LM Plus Relief Patch® ?

This is a topical hydrogel patch consisting of the local anesthetic, lidocaine, and the topical analgesic, menthol.

What is LM Plus Relief Patch® used for?

This patch is applied topically for use on normal intact skin for the temporary relief of minor aches and pains of muscles and joints, such as simple backache, lumbago, arthritis, neuralgia, strains, bruises, and sprains. Read the information sheet provided before you start using this medication and each time you get a refill. If you have any questions, please consult your doctor or pharmacist. Inform your doctor if your condition does not improve or if it worsens. The use of this medication shall be used under the supervision of a physician only as it may be used in conjunction with other therapies.

This information may not include all of the information needed to use LM Plus Relief Patch® safely and effectively.

For Topical Use Only

What are the possible side effects with LM Plus Relief Patch®

- Common: itching, redness or flaking of the skin following application (note: the majority of patients experience no significant adverse events following patch application).
- NOTE: serious side effects are, in general, related to accidental toxicity of medication by applying considerably more than directed by your doctor or pharmacist or by ingesting the contents of the patch or using this patch in conjunction with other lidocaine containing products.
- Tell your healthcare provider about all the medicines you take. This includes prescription and nonprescription medicines, vitamins, and herbal supplements.
- Avoid excessive alcohol usage, since it may increase the potential for Central Nervous System (CNS) effects such as dizziness, confusion, lightheadedness and orthostatic hypotension.

This is not a complete list of the possible side effects. For more information, talk with your doctor or pharmacist. You may report side effects to FDA at 1-800-FDA-1088 or

www.fda.gov/medwatch.

KEEP OUT OF REACH OF CHILDREN

DIRECTIONS FOR USE

Adults and children 12 years and over:

Apply 1 patch to the affected area of intact skin. LM Plus Relief Patch® should be removed after 12 hours of continuous use and remain off for at least 12 hours.

1. Determine area of patch application. If the pain area is smaller than the patch, patches may be cut into smaller sizes with scissors. Safely discard the remaining unused pieces of cut patches where children and pets cannot reach.
2. Remove the transparent release liner (clear plastic backing) before application of patches to the skin. Apply immediately after removal from the protective envelope.
3. Apply 1 patch to the affected area so that the patch covers most of the painful area. Apply patch only once during each 24-hr period (12 hours on / 12 hours off).
4. Remove patch if irritation occurs.

Children under 12 years of age: Consult a doctor

WARNINGS

FOR EXTERNAL USE ONLY

1. **Do not use**:
- More than 1 patch on your body at a time or on irritated or swollen skin
- On wounds, damaged or infected skin
- On eyes, mouth, genitals, or other mucous membranes
- With a heating pad

2. Consult physician for children under 12 years of age

3. Stop and consult your prescriber
- If condition or pain worsens
- If you are allergic to any of the ingredients in this product
- If using concurrently with any other external pain-relieving products
- If you are pregnant, planning to become pregnant, or breastfeeding
- If symptoms persist for more than 7 days, or symptoms clear up and occur again within 3 days

Call your healthcare provider right away if you get any of the following warning signs or any other unusual symptoms that concern you:
- Shortness of breath
- Swelling or numbness of the tongue or throat
- Severe headache or vomiting
- Dizziness or faintness
- Changes in vision or speech

Excessive dosage, or short interval between doses, can result in high plasma levels and serious adverse effects. Patients should be instructed to strictly adhere to the

recommended dosage and administration guidelines set forth in this literature and on your prescription label. The management of serious adverse reactions may require the use of resuscitative equipment, oxygen or other resuscitative drugs.

General information about the safe and effective use LM Plus Relief Patch®

Medicines are sometimes prescribed for purposes other than those listed in a patient information leaflet. Do not use this product for another indication unless instructed and prescribed by a physician. Do not give this drug to anyone else, even if they have the same condition. This product is intended for use as prescribed by a physician.

How should I store LM Plus Relief Patch®

Store product at room temperature at 68°F to 77°F (20°C to 25°C). Keep away from heat or sunlight. Protect from excessive moisture. Safely discard product after expiration date posted on the product label. Discard patches away from small children or animals.

DO NOT use the product after the expiration date printed on the box.

What are the active ingredients in LM Plus Relief Patch® ?

The patch consists of 3.5% lidocaine and 7% menthol.

INACTIVE INGREDIENTS

Polyvinyl alcohol, non-crystallizing sorbitol solution, polyacrylic acid, glycerin, carboxymethylcellulose sodium, colloidal silicon dioxide, titanium dioxide, propylene glycol, tartaric acid, magnesium hydroxide, sodium polyacrylate, purified water.

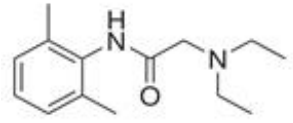
PRESCRIBER INFORMATION

LM Plus Relief Patch® (Lidocaine 3.5% / Menthol 7%)

DESCRIPTION

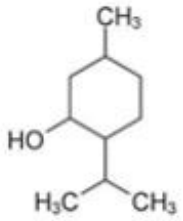
LM Plus Relief Patch® is a prescription topical patch containing 15 articulated patches or 10 articulated patches. Lidocaine is present in a 3.5% concentration (w/w). It is chemically designated as 2-(diethylamino)-N-(2,6-dimethylphenyl) acetamide and has an empirical formula of $C_{14}H_{22}N_2O$. The molecular weight of lidocaine is 234.34 g/mol. Lidocaine has an octanol: water partition ration of 43 at pH 7.4, and has the following structure:

**** Lidocaine ****



Menthol is present in a 7% concentration (w/w). The chemical name is (1R,2S,5R)-2-isopropyl-5-methylcyclohexanol. The empirical formula for Menthol is $C_{10}H_{20}O$ with a molecular weight of 156.27 g/mol. Menthol contains colorless, hexangonal crystals, usually needle-like; fused masses or crystalline powder with a pleasant, peppermint-like odor. It has a melting point between $31^{O}C$ to $36^{O}C$ and has the following structure:

**** Menthol ****



LM Plus Relief Patch® uses an adhesive hydrogel technology containing lidocaine 3.5% and menthol 7%, applied to a flexible woven polyester backing and protected by a plastic film. The protective film is removed prior to application to the skin.

CLINICAL PHARMACOLOGY

Lidocaine is a topical anesthetic and stabilizes the neuronal membrane by inhibiting the ionic fluxes required for the initiation and conduction of impulses, thereby effecting local anesthetic action.

Menthol has local anesthetic and counterirritant qualities. It also acts as a weak kappa (κ) opioid receptor agonist. Menthol chemically triggers the cold--sensitive TRPM-8 receptors in the skin, which are responsible for the well--documented cooling sensation that occurs when applied to the skin. Menthol's analgesic properties are not fully understood; however, they are mediated through a selective activation of κ-opioid receptors. Menthol also blocks voltage--sensitive sodium channels, reducing neural activity that may stimulate muscle tissue.

Menthol works by targeting the k--opioid receptor on the TRPM8 neuron. The TRPM8 neuron is normally activated at temperatures between (8°-28°C). Menthol causes the neuron to fire at temperatures above normal activation, which triggers the characteristic cooling sensation. Also because of menthol's specific targeting of the k--opioid receptor, it is endowed with analgesic properties.

Lidocaine is an amide--type local anesthetic agent and is suggested to stabilize neuronal membranes by inhibiting the ionic fluxes required for the initiation and conduction of impulses.

The penetration of Lidocaine into intact skin after application of patch is sufficient to produce an analgesic effect, but less than the amount necessary to produce a complete sensory block.

CONTRAINDICATIONS

LM Plus Relief Patch® is contraindicated in patients with a known hypersensitivity to lidocaine, or any of the topical amide-like local anesthetic preparations or to any other component of the product.

PRECAUTIONS

Because of the possibility of sedation, patients should be cautioned regarding the operation of heavy machinery or automobiles, and any activities made hazardous by

decreased alertness.

Hepatic Disease: Patients with severe hepatic disease are at greater risk of developing toxic blood concentrations of Lidocaine, because of their inability to metabolize Lidocaine normally.

Allergic Reactions: Patients allergic to para-aminobenzoic acid derivatives (procaine, tetracaine, benzocaine, etc.) have not shown cross sensitivity to Lidocaine. However, this product should be used with caution in patients with a history of drug sensitivities, especially if the etiologic agent is uncertain.

Non-intact Skin: Application to broken or inflamed skin, although not tested, may result in higher blood concentrations of Lidocaine from increased absorption. **LM Plus Relief Patch**® is only recommended for use on intact skin.

Eye Exposure: The contact of this product with the eyes, although not studied, should be avoided based on the findings of severe eye irritations with the use of similar products in animals. If eye contact occurs, immediately wash out the eye with water or saline and protect the eye until sensation returns.

External Heat Sources: Placement of external heat sources, such as heating pads or electric blankets, over patches is not recommended as this has not been evaluated and may increase plasma Lidocaine levels.

DRUG INTERACTIONS

Antiarrhythmic Drugs: LM Plus Relief Patch® should be used with caution in patients receiving Class 1 antiarrhythmic drugs (such as tocainide and mexiletine) since the toxic effects are additive and potentially synergistic.

Local Anesthetics: When **LM Plus Relief Patch**® is used concurrently with other products containing local anesthetic agents the amount absorbed from all formulations must be considered.

CARCINOGENESIS, MUTAGENESIS, IMPAIRMENT OF FERTILITY:

A minor metabolite, 2,6-xylidine, has been found to be carcinogenic in rats. The blood concentration of this metabolite is negligible following application of topical lidocaine. The effect of **LM Plus Relief Patch**® on fertility has not been studied.

PREGNANCY:

The safety of **LM Plus Relief Patch®** has not been established during pregnancy. There are no well-controlled studies in pregnant women. **LM Plus Relief Patch**® should not be used during pregnancy unless absolutely needed and discussed with a physician.

NURSING MOTHERS

The effect of **LM Plus Relief Patch®** on the nursing infant has not been evaluated. Caution should be exercised when **LM Plus Relief Patch**® is administered to a nursing mother.

PEDIATRIC / GERIATRIC USE

Safety and effectiveness in pediatric and geriatric patients have not been established.

ADVERSE REACTIONS

The most common adverse reactions are application site reactions, including dermatitis, itching or scaling. These tend to be dose-limiting and diminish with time.

Serious adverse experiences following the administration of **LM Plus Relief Patch®** are similar in nature to those observed in other amide anesthetic-containing agents. These adverse experiences are, in general, dose-related and may result from high plasma levels caused by excessive dosage, rapid absorption, or may result from hypersensitivity, idiosyncrasy, or a diminished tolerance on the part of the patient. Serious adverse experiences are generally systemic in nature.

OVERDOSAGE

There have been no reports of over-dosage with **LM Plus Relief Patch®**. Signs of overdosage would include vomiting, drowsiness, coma, respiratory depression, and seizures. In the case of an overdosage, discontinue the product immediately, treat the patient symptomatically, and institute supportive measures.

HOW SUPPLIED

LM Plus Relief Patch® is supplied in the following dosage form:
15 Patches [(5 per Re-sealable Pouch) x 3]

Rx Only

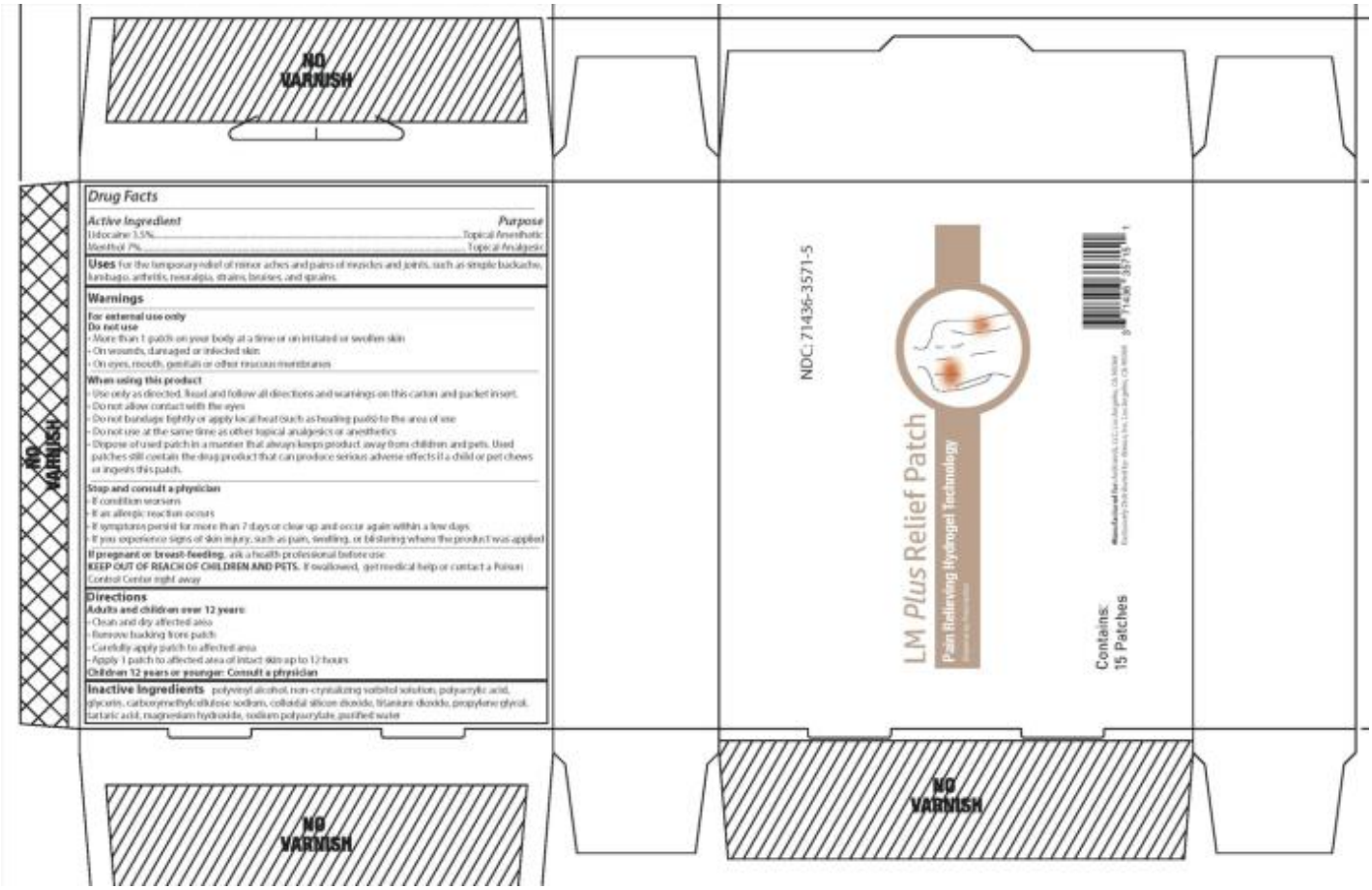
Manufactured for:
AriBrands, LLC
2317 Cotner Ave
Los Angeles, CA 90064
310.294.8956

Exclusively Distributed by:
Alexso, Inc
Los Angeles, CA 90064

NDC: 71436-3571-5 Size: 15 Patches

PRINCIPAL DISPLAY PANEL

NDC 71436-3571-5
LM PLUS RELIEF PATCH
Dispense by Prescription
Lidocaine 3.5% + Menthol 7%
15 PATCHES



LM PLUS RELIEF

lidocaine and menthol patch

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:71436-3571
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
LIDOCAINE (UNII: 98PI200987) (LIDOCAINE - UNII:98PI200987)	LIDOCAINE	490 mg
MENTHOL (UNII: L7T10EIP3A) (MENTHOL - UNII:L7T10EIP3A)	MENTHOL	980 mg

Inactive Ingredients	
Ingredient Name	**Strength**
POLYVINYL ALCOHOL, UNSPECIFIED (UNII: 532B59J990)	
NONCRYSTALLIZING SORBITOL SOLUTION (UNII: 9E0S3UM200)	
POLYACRYLIC ACID (8000 MW) (UNII: 73861X4K5F)	
GLYCERIN (UNII: PDC6A3C0OX)	
CARBOXYMETHYLCELLULOSE SODIUM (UNII: K679OBS311)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	

PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
TARTARIC ACID (UNII: W4888I119H)	
MAGNESIUM HYDROXIDE (UNII: NBZ3QY004S)	
SODIUM POLYACRYLATE (8000 MW) (UNII: 285CYO341L)	
WATER (UNII: 059QF0KO0R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:71436-3571-5	3 in 1 CARTON	09/01/2023	
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
unapproved drug other		09/01/2023	

Labeler - ARI BRANDS, LLC (080658382)

Revised: 9/2023 ARI BRANDS, LLC