LIDOPRO PATCH- lidocaine, menthol, methyl salicylate patch
Advanced Rx Pharmacy of Tennessee, LLC

LidoPro Patch

Methemoglobinemia

Cases of methemoglobinemia have been reported in association with local anesthetic use. Although all patients are at risk for methemoglobinemia, patients with glucose-6-phosphate dehydrogenase deficiency, congenital or idiopathic methemoglobinemia, cardiac or pulmonary compromise, infants under 6 months of age, and concurrent exposure to oxidizing agents or their metabolites are more susceptible to developing clinical manifestations of the condition. If local anesthetics must be used in these patients, close monitoring for symptoms and signs of methemoglobinemia is recommended.

Signs and symptoms of methemoglobinemia may occur immediately or may be delayed some hours after exposure and are characterized by a cyanotic skin discoloration and abnormal coloration of the blood. Methemoglobin levels may continue to rise; therefore, immediate treatment is required to avert more serious central nervous system and cardiovascular adverse effects, including seizures, coma, arrhythmias, and death. Discontinue lidocaine-containing products and any other oxidizing agents. Depending on the severity of the symptoms, patients may respond to supportive care, i.e., oxygen therapy, hydration. More severe symptoms may require treatment with methylene blue, exchange transfusion, or hyperbaric oxygen.

Lidocaine 4% - Topical Analgesic

Menthol 5% - Topical Analgesic

Methyl Salicylate 4% - Topical Analgesic

Topical Analgesic

Uses

Temporarily relieves mild to moderate aches and pains of muscles and joints associated with:

• muscle soreness

• strains

• sprains

• arthritis

• simple backache

• muscle stiffness

• bruises

For external use only

Stomach bleeding warning

This product contains an NSAID, which may cause stomach bleeding. The chance is small, but higher if you

• are age 60 or older

• have had stomach ulcers or bleeding problems

• take other drugs containing an NSAID (Aspirin, Ibuprofen, Naproxen, or others)

• take a blood thinning (anticoagulant) or steroid drug

• have three or more alcoholic drinks every day while using this product

• take more or for a longer time than directed

Do not use

• on the face or rashes; on wounds or damaged skin

• in the eyes, mouth, or other mucous membranes

• on genitals

• with a heating pad

• if allergic to any NSAIDS

• right before or after heart surgery

• any patch from a pouch that has been opened for 7 or more days

Ask a doctor before use if

• you are allergic to topical products

• the stomach bleeding warning applies to you

• you are taking a diuretic

• you have high blood pressure, heart disease, or kidney disease

• you are pregnant

When using this product

• wash hands after applying or removing patch

• avoid contact with eyes. If eye contact occurs, rinse thoroughly with water

• the risk of heart attack or stroke may increase if you use more than directed or for longer than directed.

Stop use and consult your physician if

• stomach pain or upset gets worse or lasts

• rash, irritation, or itching develops

• you feel faint, vomit blood, or have bloody or black stools (these are signs of stomach bleeding)

• condition worsens

If pregnant or breast feeding,

ask a doctor before use while breast feeding and during the first 6 months of pregnancy. Do not use during last 3 months of pregnancy because it may cause problems in the unborn child or complications during delivery.

Keep out of reach of children.

If put in mouth, get medical help or contact a Poison Control Center right away. Package not child resistant. Dispose of the used patches by folding sticky ends together.

Directions

Adults 18 years and older:

• Apply patch to affected area 1 to 2 times daily or as directed.

• clean and dry affected area

• open pouch and remove one patch containing medical adhesive backing

• remove protective film from both patch and medical adhesive

• apply one patch to the affected area of pain and leave in place for 8 to 12 hours

• if pain lasts after using the first patch, a second patch may be applied for up to another 8 to 12 hours

• only use one patch at a time

• do not use more than 2 patches per day

• wash hands with soap and water after applying or removing patch

• reseal pouch containing unused patches after each use

Children under 18 years of age: Do not use

• some individuals may not experience pain relief until several minutes or hours after applying the patch

• avoid storing product in direct sunlight

• protect product from excessive moisture

• store at 67-77°F (19-25°C)

Acrylic Acid, Aluminum Hydroxide, Carmellose Sodium, 2-Ethylhexyl Acrylate, Glycerin, Isopropyl Myristate, Methyl Acrylate, Nonoxynol-30, Polyacrylic Acid, Polysorbate 80, Sodium Polyacrylate, Sorbitan Sesquioleate, Starch, Talc, Tartaric Acid, Titanium Dioxide, Water

Manufactured For:

Terrain Pharmaceuticals

Reno, NV 89501

Formulated and Designed in Nevada

Assembled in China

Patent Pending

LidoProTM patch

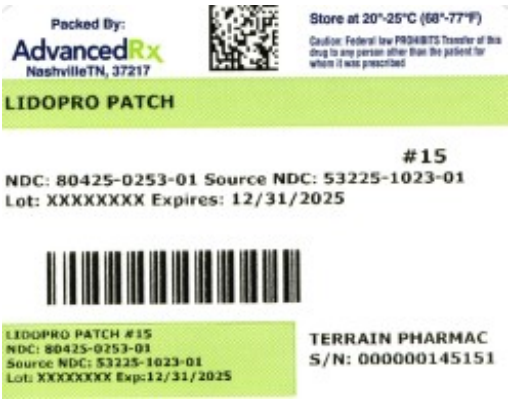
For questions or comments, call

877-985-8377

As directed

Keep out of Reach of Children

As Directed



LIDOPRO PATCH

lidocaine, menthol, methyl salicylate patch

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:80425-0253(NDC:53225-1023)
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
LIDOCAINE HYDROCHLORIDE (UNII: V13007Z41A) (LIDOCAINE - UNII:98PI200987)	LIDOCAINE HYDROCHLORIDE ANHYDROUS	4 mg in 100 mg
MENTHOL (UNII: L7T10EIP3A) (MENTHOL - UNII:L7T10EIP3A)	MENTHOL	5 mg in 100 mg
METHYL SALICYLATE (UNII: LAV5U5022Y) (SALICYLIC ACID - UNII:O414PZ4LPZ)	METHYL SALICYLATE	4 mg in 100 mg

Inactive Ingredients	
Ingredient Name	**Strength**
CARBOXYMETHYLCELLULOSE SODIUM (UNII: K679OBS311)	
2-ETHYLHEXYL ACRYLATE (UNII: HR49R9S6XG)	
ALUMINUM HYDROXIDE (UNII: 5QB0T2IUN0)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:80425-0253-1	15 in 1 BOX	05/03/2023	
1		5 in 1 POUCH		
1		8500 mg in 1 PATCH; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M017	05/03/2023	

Labeler - Advanced Rx Pharmacy of Tennessee, LLC (117023142)

Establishment

Name	Address	ID/FEI	Business Operations
Advanced Rx Pharmacy of Tennessee, LLC		117023142	repack(80425-0253)

Revised: 3/2024 Advanced Rx Pharmacy of Tennessee, LLC