LIDOSYNC- lidocaine 4%, menthol 1%, methyl salicylate 2% patch lon Pharma, LLC

LIDOSYNC

Lidocaine 4%, Menthol 1%, Methyl Salicylate 2%

TOPICAL PAIN PATCH For Temporary Pain Relief

Drug Facts

Active Ingredient(in each patch)

Lidocaine 4%

Menthol 1%

Methyl salicylate 2%

Purpose

Topical anesthetic

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

Warnings

For external use only

Stomach bleeding warning: This product contains a NSAID, which may cause stomach bleeding. The chance is small.but higher if you

- are aged 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 steroidal 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

- More than one patch on your body at a time
- On cut, irritated or swollen skin
- On puncture wounds
- If you are allergic to any active or inactive ingredients
- If pouch is damaged or opened.

When using this product

- Use only as directed
- Read and follow all directions and warnings
- Do not allow to contact with the eyes
- Do not use at the same time as other topical analgesics
- Do not bandage tightly or apply local heat(such as heating pads)to the area of use
- Do not microwave
- Dispose of used patch in manner that always keeps product away from children and pets. Used patches still contain the drug product that can produce serious adverse effects if a child or pet chews or ingests this patch.

Stop use and consult a doctor if

- Condition worsens
- Redness is present
- Irritation develops
- Symptoms persist for more than 7 days or clear up and occur again within a few days
- You experience signs of skin injury, such as pain, swelling or blistering where the product was applied
- Stomach pain or upset gets worse or lasts
- You feel faint, vomit blood, or have bloody or black stools (these are signs of stomach bleeding).

If pregnant or breastfeeding, ask a health professional before use.

Keep out of reach of children and pets. If swallowed, get medical help or contact a Poison Control Center right away.

Directions

Adults, or children over the age of 12:Clean and dry affected area.

Apply sticky side of patch to affected area and leave in place for 8 hours. If pain lasts after using the first patch, a second patch may be applied. 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 immediately after each use. Children under 12 years of age: Do not use.

Other information

- Store at 68°F-77°F (20 °C-25°C).
- Store in a clean, dry place without direct sunlight. Protect from excessive moisture.

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

Inactive Ingredients

Arnica Montana Flower Extract, Dihydroxyaluminum Aminoacetate, Edetate Disodium, Glycerin, Hydroxyacetophenone, Kaolin, L-tartaric Acid, Mineral Oil, Polyacrylic Acid, Propylene Glycol, Polysorbate 80, PVP, Sodium Polyacrylate, Titanium Dioxide, Water.

Questions or Comments:833.711.8833

• info@ionpharmausa.com

PRINCIPAL DISPLAY PANEL

NDC 82944-102-10

LIDOSYNC

Lidocaine 4%, Menthol 1%, Methyl Salicylate 2%

TOPICAL PAIN PATCH

For Temporary Pain Relief

Flexible Patch Innovation

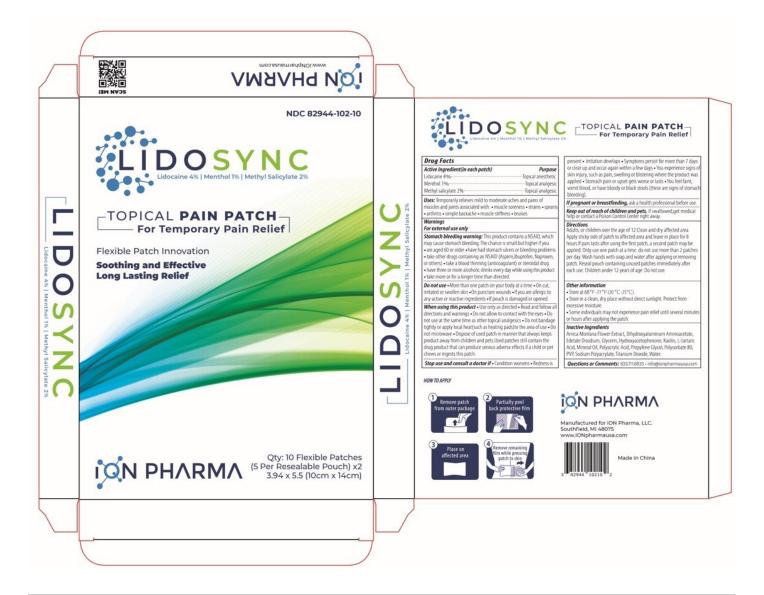
Soothing and Effective Long Lasting Relief

Qty: 10 Flexible Patches

(5 per Resealable Pouch) x2

3.94 x 5.5 (10cm x 14cm)

ION PHARMA



LIDOSYNC

lidocaine 4%, menthol 1%, methyl salicylate 2% patch

Product Information Product Type HUMAN OTC DRUG Item Code (Source) NDC:82944-102 Route of Administration TOPICAL

Active Ingredient/Active Moiety				
Ingredient Name	Basis of Strength	Strength		
LIDOCAINE (UNII: 98PI200987) (LIDOCAINE - UNII:98PI200987)	LIDOCAINE	4 g		
MENTHOL (UNII: L7T10EIP3A) (MENTHOL - UNII:L7T10EIP3A)	MENTHOL	1 g		
METHYL SALICYLATE (UNII: LAV5U5022Y) (SALICYLIC ACID - UNII:O414PZ4LPZ)	METHYL SALICYLATE	2 g		

Inactive Ingredients			
Ingredient Name	Strength		
ARNICA MONTANA FLOWER (UNII: OZ0E5Y15PZ)			

DIHYDROXYALUMINUM AMINOACETATE (UNII: DO250MG0W6)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	
GLYCERIN (UNII: PDC6A3C0OX)	
HYDROXYACETOPHENONE (UNII: G1L3HT4CMH)	
KAOLIN (UNII: 24H4NWX5CO)	
TARTARIC ACID (UNII: W4888I119H)	
MINERAL OIL (UNII: T5L8T28FGP)	
POLYACRYLIC ACID (450000 MW) (UNII: KD3S7H73D3)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
POLYSORBATE 80 (UNII: 60ZP39ZG8H)	
POVIDONE, UNSPECIFIED (UNII: FZ989GH94E)	
SODIUM POLYACRYLATE (2500000 MW) (UNII: 05I15JNI2J)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
WATER (UNII: 059QF0KO0R)	

P	Packaging					
#	Item Code	Package Description	Marketing Start Date	Marketing End Date		
1	NDC:82944-102- 10	10 in 1 BOX	06/01/2023			
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	
OTC Monograph Drug	M017	06/01/2023		

Labeler - Ion Pharma, LLC (118739596)

Revised: 9/2024 Ion Pharma, LLC