

LIDOREAL PATCH - lidocaine and menthol patch
FORREAL PHARMACEUTICALS LLC

LidoReal Patch

Drug Facts

Active Ingredient

Lidocaine 4%

Purpose

Topical Anesthetic

Active Ingredient

Menthol 1%

Purpose

Topical Analgesic

Uses

For the temporary relief of pain.

Warnings

For external use only

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
- right before or after heart surgery
- any patch from a pouch that has been opened for 7 or more days
- in large quantities, particularly over raw surfaces or blistered areas
- if tamper-evident seal is torn, broken, or missing
- more than 2 patches per day unless directed by a doctor
- children under 18 years of age

Ask a doctor before use if you have

- allergies to topical products

- high blood pressure, heart disease, or kidney disease.

When using this product

- 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 a doctor if

condition worsens, or if symptoms persist for more than 7 days or clear up and occur again within a few days.

If pregnant or breast feeding, ask a health professional before use.

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, seek medical help or contact a Poison Control Center right away. Dispose of the used patches by folding sticky ends together.

Directions

Adults 18 years and older:

- clean and dry affected area
- open pouch and remove one patch
- remove protective film from patch
- 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
- wash hands with soap and water after applying or removing patch
- reseal pouch containing unused patches after each use

Other information

- 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)

Inactive Ingredients

dihydroxyaluminum aminoacetate, edetate disodium, glycerin, hydroxyacetophenone, kaolin, mineral oil, polyacrylic acid, polysorbate 80, polyvinyl pyrrolidone, propylene glycol, sodium polyacrylate, tartaric acid, titanium dioxide, water

Questions?

877-367-3250

Principal Display Panel

NDC 81877-725-15

Forreal Pharmaceuticals

YOUR SOLUTION TO BETTER HEALTHCARE.

LIDOREAL

Lidocaine 4% and Menthol 1% Patch

15 PATCHES

10 cm x 14 cm each



LIDOREAL PATCH

lidocaine and menthol patch

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:81877-725
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
LIDOCAINE (UNII: 98PI200987) (LIDOCAINE - UNII:98PI200987)	LIDOCAINE	4 mg
MENTHOL (UNII: L7T10EIP3A) (MENTHOL - UNII:L7T10EIP3A)	MENTHOL	1 mg

Inactive Ingredients

Ingredient Name	Strength
DIHYDROXYALUMINUM AMINOACETATE ANHYDROUS (UNII: 1K713C615K)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	
GLYCERIN (UNII: PDC6A3C0OX)	
HYDROXYACETOPHENONE (UNII: G1L3HT4CMH)	
KAOLIN (UNII: 24H4NWX5CO)	
MINERAL OIL (UNII: T5L8T28FGP)	
POLYACRYLIC ACID (250000 MW) (UNII: 9G2MAD7J6W)	
POLYSORBATE 80 (UNII: 6OZP39ZG8H)	
POVIDONE K90 (UNII: RDH86HJV5Z)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
SODIUM POLYACRYLATE (2500000 MW) (UNII: 05I15JN12J)	
TARTARIC ACID (UNII: W4888I119H)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
WATER (UNII: 059QF0KO0R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:81877-725-15	15 in 1 BOX; Type 0: Not a Combination Product	05/15/2024	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M017	05/15/2024	

Labeler - FORREAL PHARMACEUTICALS LLC (118029197)

