LIDOCAINE- lidocaine patch
PHARMACURE LLC

Active Ingredient

Lidocaine 4%

Purpose

Topical Anesthetic

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

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

Ask a doctor before use ifyou are allergic to topical products, you are taking a diuretic, you have high blood pressure, heart disease, kidney disease, or 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.

Stop use and consult your physician if rash, irritation, or itching develops, or condition worsens.

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

For external use only

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

Directions

Adults and children 12 years and over: apply 1 to 2 patches to the affected area of intact skin. Lidocaine patch should be removed after 12 hours of continuous use and remain off for at least 12 hours.

INSTRUCTIONS FOR USE

- 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
- Remove the transparent protective film (clear plastic barrier) before application of patches to the skin
- Apply immediately after removing the protective film Apply 1 patch to the affected area so that the patch covers all or most of the painful area
- Remove patch if irritation occurs

Children under 12 years of age: Consult a doctor.

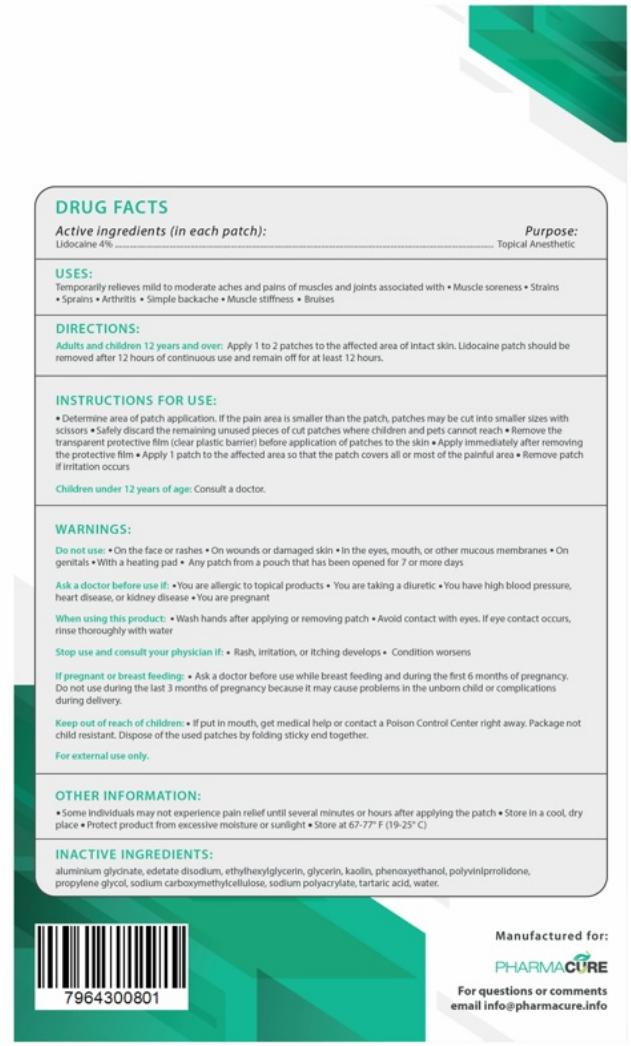
Other information

Some individuals may not experience pain relief until several minutes or hours after applying the patch. Store in a cool, dry place. Protect the product from excessive moisture or sunlight. Store at 67-77°F (19-25°C).

Inactive ingredients

aluminium glycinate, edetate disodium, ethylhexylglycerin, glycerin, kaolin, phenoxyethanol, polyvinlprrolidone, propylene glycol, sodium carboxymethylcellulose, sodium polyacrylate, tartaric acid, water

Product label



LIDOCAINE

lidocaine patch

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:79643-008
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
LIDOCAINE (UNII: 98PI200987) (LIDOCAINE - UNII:98PI200987)	LIDOCAINE	4 g in 100 g

Inactive Ingredients	
Ingredient Name	**Strength**
ALUMINUM GLYCINATE (UNII: 1K713C615K)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	
ETHYLHEXYLGLYCERIN (UNII: 147D247K3P)	

GLYCERIN (UNII: PDC6A3C0OX)	
KAOLIN (UNII: 24H4NWX5CO)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
POVIDONE, UNSPECIFIED (UNII: FZ989GH94E)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
CARBOXYMETHYLCELLULOSE SODIUM, UNSPECIFIED (UNII: K679OBS311)	
SODIUM POLYACRYLATE (2500000 MW) (UNII: 05I15JNI2J)	
TARTARIC ACID (UNII: W4888I119H)	
WATER (UNII: 059QF0KO0R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:79643-008-01	10 in 1 BOX	01/24/2025	
1		14 g 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	01/24/2025	

Labeler - PHARMACURE LLC (055983858)

Revised: 1/2025 PHARMACURE LLC