

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 if you 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 or 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.

Inactive ingredients

dihydroxyaluminum aminoacetate, edetate disodium, glycerin, isopropyl myristate, polyacrylic acid, propyl p-hydroxybenzoate, propylene glycol, sodium polyacrylate, tartaric acid, titanium dioxide, tween 80, water

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).

Product label

DRUG FACTS

Active ingredients (in each patch):

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

DIRECTIONS:

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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 if: • You are allergic to topical products • 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

Stop use and consult your physician if: • Rash, irritation, or itching develops • 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 the 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 end together.

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OTHER INFORMATION:

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INACTIVE INGREDIENTS:

dihydroxyaluminum aminoacetate, edetate disodium, glycerin, isopropyl myristate, polyacrylic acid, propyl p-hydroxybenzoate, propylene glycol, sodium polyacrylate, tartaric acid, titanium dioxide, tween 80, water.



Manufactured for:

PHARMACURE

For questions or comments
email info@pharmacure.info

LIDOCAINE 4% PATCH

EXTERNAL ANESTHETIC
PAIN RELIEF

10 PATCHES
NDC: 79643-005-01

LIDOCAINE

lidocaine patch

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:79643-005
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
DIHYDROXYALUMINUM AMINOACETATE (UNII: DO250MG0W6)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	
GLYCERIN (UNII: PDC6A3C0OX)	
ISOPROPYL MYRISTATE (UNII: 0RE8K4LNJS)	
POLYACRYLIC ACID (250000 MW) (UNII: 9G2MAD7J6W)	
PROPYLPARABEN (UNII: Z8IX2SC1OH)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	

SODIUM POLYACRYLATE (2500000 MW) (UNII: 05I15JN12J)				
TARTARIC ACID (UNII: W4888I119H)				
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)				
POLYSORBATE 80 (UNII: 6OZP39ZG8H)				
WATER (UNII: 059QF0KO0R)				
Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:79643-005-01	10 in 1 BOX	11/29/2024	
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	11/29/2024		

Labeler - PHARMACURE LLC (055983858)

Revised: 12/2024

PHARMACURE LLC