

LIDOCAINE PAIN RELIEVING- lidocaine patch

Unexo Life Sciences Private Limited

Disclaimer: Most OTC drugs are not reviewed and approved by FDA, however they may be marketed if they comply with applicable regulations and policies. FDA has not evaluated whether this product complies.

Lidocaine Pain Relieving Patch

Drug Facts

Active Ingredient

Lidocaine 4.0%

Topical anesthetic

Uses

Temporarily relieves minor pain.

Warnings

For external use only

Do not use

- More than one patch on your body at a time
- On cut, irritated or swollen skin
- On puncture wounds
- For more than one week without consulting a doctor
- 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 on this pack
- Do not allow 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 ask 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

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

Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center (1-800-222-1222) right away.

Directions

- **Adults and children over 12 years:** Clean and dry affected area. Remove film from patch (see illustration). Apply sticky side of patch to affected area. Use one patch for up to 12 hours. Discard patch after single use
- **Children 12 years of age or younger:** Consult a physician.

Other Information

Store in a clean, dry place outside of direct sunlight. Protect from excessive moisture.

Inactive Ingredients

aluminum glycinate, glycerin, kaolin, methylparaben, polyacrylic acid, polysorbate 80, propylene glycol, propylparaben, PVP, sodium polyacrylate, tartaric acid, titanium dioxide, water

Questions or Comments

Call 1-888-287-1915

Manufactured By:

UNEXO LIFE SCIENCES PVT. LTD.
B-16. Sector 4, Bawana Industrial Area,
Delhi - 110039 (INDIA)

PRINCIPAL DISPLAY PANEL - 1 Patch Pouch Label

NDC: 71391-150-01

LIDOCAINE
PAIN
RELIEVING
PATCH

LIDOCAINE 4% / Topical Anesthetic

Temporarily relieves pain
Stay-Put flexible Patch

Easy to apply & remove
No-mess, single use application
Odor-free

Lasts upto 12 hours

1 PATCH
3.93 X 5.5 IN
(10cm X 14cm)

NDC: 71391-150-01

LIDOCAINE PAIN RELIEVING PATCH

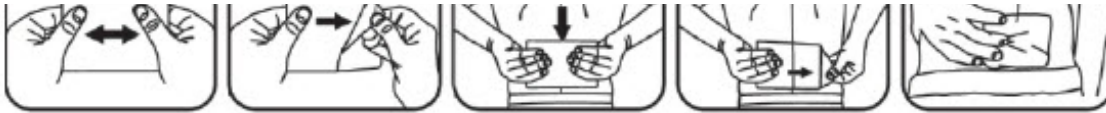
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Questions or Comments Call +91 9212228401

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UNEXO LIFE SCIENCES PVT. LTD.
 B-16, Sector 4, Bawana Industrial Area,
 Delhi - 110039 (INDIA)
 Phone: +91 9212228401
 Email: info@unexopharma.com

Made in India
NC/DL-378-A&U

NDC: 71391-150-01

LIDOCAINE PAIN RELIEVING

lidocaine patch

Product Information

Product Type

HUMAN OTC DRUG

Item Code (Source)

NDC:71391-150

Route of Administration TOPICAL

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
Lidocaine (UNII: 98PI200987) (LIDOCAINE - UNII:98PI200987)	Lidocaine	344 mg

Inactive Ingredients

Ingredient Name	Strength
DIHYDROXYALUMINUM AMINOACETATE ANHYDROUS (UNII: 1K713C615K)	
Glycerin (UNII: PDC6A3C00X)	
Kaolin (UNII: 24H4NWX5CO)	
Methylparaben (UNII: A218C7HI9T)	
POLYACRYLIC ACID (250000 MW) (UNII: 9G2MAD7J6W)	
Polysorbate 80 (UNII: 6OZP39ZG8H)	
Propylene Glycol (UNII: 6DC9Q167V3)	
Propylparaben (UNII: Z8IX2SC1OH)	
POVIDONE, UNSPECIFIED (UNII: FZ989GH94E)	
SODIUM POLYACRYLATE (8000 MW) (UNII: 285CYO341L)	
Tartaric Acid (UNII: W4888I119H)	
Titanium Dioxide (UNII: 15FIX9V2JP)	
Water (UNII: 059QF0KO0R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:71391-150-01	1 in 1 POUCH; Type 0: Not a Combination Product	02/01/2022	
2	NDC:71391-150-05	5 in 1 BOX	02/01/2022	
2	NDC:71391-150-01	1 in 1 POUCH; Type 0: Not a Combination Product		
3	NDC:71391-150-06	6 in 1 BOX	02/01/2022	
3	NDC:71391-150-01	1 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 not final	part348	02/01/2022	

Labeler - Unexo Life Sciences Private Limited (872260479)

Establishment

Name	Address	ID/FEI	Business Operations
Unexo Life Sciences Private Limited		872260479	MANUFACTURE(71391-150)

Revised: 2/2022

Unexo Life Sciences Private Limited