

**PAIN RELIEF 4% LIDOCAINE- 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.*

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**Pain Relief 4% Lidocaine Patch**

**Drug Facts**

**Active Ingredient**

Lidocaine 4.0%

**Purpose**

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, benzyl alcohol, ethylhexylglycerin, glycerin, kaolin, methylparaben, phenoxyethanol, polyacrylic acid, polysorbate 80, propylene glycol, propylparaben, PVP, sodium polyacrylate, tartaric acid, titanium dioxide, water

**Questions or Comments**

**Call +91 9212228401**

***Manufactured By:***

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

**PRINCIPAL DISPLAY PANEL - One Patch Pouch**

NDC: 71391-151-01

PAIN RELIEF  
4% LIDOCAINE PATCH

Desensitizes aggravated nerves  
and relieves pain

No-mess  
 Single-use application  
 Easy to apply and remove  
 Stay-put flexible gel patch  
 Unscented

1 PATCH  
 3.93 X 5.51 IN  
 (10cm X 14cm)

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**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 carton ■ 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 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.  
 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 1-800-222-1222 right away.

**Directions**  
 Adults and children 12 years of age and over: Clean and dry affected area. Carefully remove backing from patch starting at a corner. Apply sticky side of patch to affected area. Use one patch for up to 12 hours. Discard patch after single use. Children under 12 years of age: consult a physician.

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

**Inactive ingredients**  
 aluminum glycolate, benzyl alcohol, ethylhexylglycerin, glycerin, kaolin, phenoxethanol, polysorbate 80, polyorbate 80, propylene glycol, PVP, sodium polyacrylate, tartaric acid, titanium dioxide, water

Manufactured By:  
 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: 71391-151-01

## PAIN RELIEF 4% LIDOCAINE

lidocaine patch

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:71391-151
<b>Route of Administration</b>	TOPICAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
<b>Lidocaine</b> (UNII: 98PI200987) (Lidocaine - UNII:98PI200987)	Lidocaine	344 mg

## Inactive Ingredients

Ingredient Name	Strength
<b>DIHYDROXYALUMINUM AMINOACETATE ANHYDROUS</b> (UNII: 1K713C615K)	
<b>Benzyl Alcohol</b> (UNII: LKG8494WBH)	
<b>Ethylhexylglycerin</b> (UNII: 147D247K3P)	
<b>Glycerin</b> (UNII: PDC6A3C0OX)	
<b>Kaolin</b> (UNII: 24H4NWX5CO)	
<b>Phenoxyethanol</b> (UNII: HIE492ZZ3T)	
<b>POLYACRYLIC ACID (250000 MW)</b> (UNII: 9G2MAD7J6W)	
<b>Polysorbate 80</b> (UNII: 6OZP39ZG8H)	
<b>Propylene Glycol</b> (UNII: 6DC9Q167V3)	
<b>POVIDONE, UNSPECIFIED</b> (UNII: FZ989GH94E)	
<b>SODIUM POLYACRYLATE (8000 MW)</b> (UNII: 285CYO341L)	
<b>Tartaric Acid</b> (UNII: W4888I119H)	
<b>Titanium Dioxide</b> (UNII: 15FIX9V2JP)	
<b>Water</b> (UNII: 059QF0KO0R)	

## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:71391-151-01	1 in 1 POUCH; Type 0: Not a Combination Product	08/15/2022	
2	NDC:71391-151-05	5 in 1 BOX	08/15/2022	
2	NDC:71391-151-01	1 in 1 POUCH; Type 0: Not a Combination Product		
3	NDC:71391-151-06	6 in 1 BOX	08/15/2022	
3	NDC:71391-151-01	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	08/15/2022	

**Labeler** - Unexo Life Sciences Private Limited (872260479)

## Establishment

Name	Address	ID/FEI	Business Operations
Unexo Life Sciences Private Limited		872260479	MANUFACTURE(71391-151)