NULIDO LIDOCAINE PATCH PLUS MENTHOL- lidocaine, menthol patch All Pharma LLC

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.

NULIDO Lidocaine Patch Plus Menthol

Drug Facts

Lidocaine 4% Topical Anesthetic Menthol 1% Topical Anesthetic Topical Anesthetic

USES

Temporary relief of minor pain

WARNINGS

- For External use only. Use only as directed.
- Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.
- 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.

If pregnant or breast feeding

• Contact a physician prior to use.

WHEN USING:

- 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.

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 after single use. Children under 12 years of age: consult a physician.

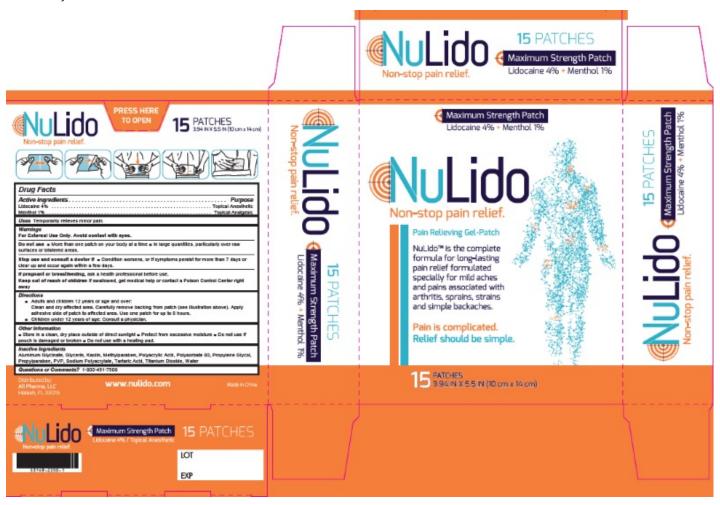
INACTIVE INGREDIENTS

aluminum glycinate, glycerin, kaolin, methylparaben, polyacrylic acid, polysorbate 80, propylene glycol,

propylparaben, PVP, sodium polyacrylate, tartaric acid, titanium dioxide, water

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

DIST. BY All Pharma LLC Hialeah, FL 33016



NULIDO LIDOCAINE PATCH PLUS MENTHOL

lidocaine, menthol patch

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:53149-2200
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
LIDO CAINE (UNII: 98 PI200987) (LIDO CAINE - UNII:98 PI200987)	LIDOCAINE	4 g in 100 g	
MENTHOL, UNSPECIFIED FORM (UNII: L7T10EIP3A) (MENTHOL - UNII:L7T10EIP3A)	MENTHOL, UNSPECIFIED FORM	1 g in 100 g	

Inactive Ingredients	
Ingredient Name	Strength
DIHYDRO XYALUMINUM AMINO ACETATE ANHYDRO US (UNII: 1K713C615K)	
GLYCERIN (UNII: PDC6A3C0OX)	
KAOLIN (UNII: 24H4NWX5CO)	
METHYLPARABEN (UNII: A2I8 C7HI9 T)	
POLYACRYLIC ACID (250000 MW) (UNII: 9G2MAD7J6W)	
POLYSORBATE 80 (UNII: 6OZP39ZG8H)	
PROPYLENE GLYCOL 1-(2-METHYLBUTYRATE) (UNII: 9Q5W5G6461)	
PROPYLPARABEN (UNII: Z8IX2SC1OH)	
PO VIDONE, UNSPECIFIED (UNII: FZ989GH94E)	
SODIUM POLYACRYLATE (2500000 MW) (UNII: 05I15JNI2J)	
TARTARIC ACID (UNII: W48881119 H)	
TITANIUM DIO XIDE (UNII: 15FIX9 V2JP)	
WATER (UNII: 059QF0KO0R)	

	Packaging				
:	# Item Code	Package Description	Marketing Start Date	Marketing End Date	
	NDC:53149 - 2200 - 1	15 in 1 POUCH	07/01/2018		
	1	8 g in 1 PATCH; Type 2: Prefilled Drug Delivery Device/System (syringe, patch, etc.)			

Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
OTC monograph not final	part348	07/01/2018		

Establishment				
Name	Address	ID/FEI	Business Operations	
Foshan Aqua Gel Biotech Co.,Ltd.		529128763	manufacture(53149-2200)	

Revised: 12/2017 All Pharma LLC