

MAXIMUM STRENGTH LIDOCAINE PATCH- lidocaine patch

Intermed

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.

Maximum Strength Lidocaine Patch- Bulk Listing

Active Ingredient

Lidocaine 4%

Purpose

Topical Anesthetic

Uses

Temporarily relieves minor pain

Warnings

For external use only

Do Not Use

- more than 1 patch on your body at a time or on cut, irritated or swollen skin
- on puncture wounds
- for more than one week without consulting a doctor

When Using This Product

- use only as directed. Read and follow all directions and warnings on this label.
- do not allow contact with the eyes
- do not bandage tightly or apply local heat (such as heating pads) to the area of use
- do not use at the same time as other topical analgesics
- dispose of used patch in manner that always keeps product away from children or 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 and Pets

If swallowed, get medical help or contact a Poison Control Center right away.

Directions

Adults and children over 12 years:

- clean and dry affected area
- remove backing from patch by firmly grasping both ends and gently pulling until backing separates in middle
- carefully remove smaller portion of backing from patch and apply exposed portion of patch to affected area
- once exposed portion of patch is positioned, carefully remove remaining backing to completely apply patch to affected area
- use 1 patch for up to 12 hours

children 12 years or younger: ask a doctor

Directions

Adults and children over 12 years:

- clean and dry affected area
- remove backing from patch by firmly grasping both ends and gently pulling until backing separates in middle
- carefully remove smaller portion of backing from patch and apply exposed portion of patch to affected area
- once exposed portion of patch is positioned, carefully remove remaining backing to completely apply patch to affected area
- use 1 patch for up to 12 hours

children 12 years or younger: ask a doctor

Inactive Ingredients

Dihydroxyaluminium aminoacetate, disodium EDTA, glycerin, methylparaben, polyvinyl alcohol, propyl

paraben, propylene glycol, purified water, sodium carboxymethyl cellulose, sodium polyacrylate, tartaric

acid, titanium dioxide.

Bulk Package Label

Qty : 100x6's = 600 Patches

Case No :

**PAIN RELIEVING PATCH
MAXIMUM STRENGTH**

4% LIDOCAINE

Unscented

Active Ingredients : Lidocaine.....4%

Storage : Store product at room temperature, do not exceed 30°C(86°F)
Protect product from direct sunlight and excessive moisture

Batch No. :

Mfg. Date :

Exp. Date :

Gross Weight :

Net Weight :

Code : TN/DRUGS/22/1999

Manufacturer Name : **INTERMED**

Manufacturer Address : No 4, GK Industrial Estate,
Arcot Road, Porur, Chennai-600116
INDIA

Manufacturer Labeller Code : 71811

Consignee Labeller Code : 76168

Consignee:

Velocity Pharma LLC,
Farmingdale, NY 11735

Barcode

Label size : L-28cmxH-16cm

Qty : 100x5's = 500 Patches

Case No :

**ODORLESS LIDOCAINE
PAIN RELIEVING PATCH
MAXIMUM STRENGTH**

LIDOCAINE 4%

Active Ingredients : Lidocaine.....4%

Storage : Store product at room temperature, do not exceed 30°C(86°F)
Protect product from direct sunlight and excessive moisture

Batch No. :

Mfg. Date :

Exp. Date :

Gross Weight :

Net Weight :

Code : TN/DRUGS/22/1999

Manufacturer Name : **INTERMED**

Manufacturer Address : No 4, GK Industrial Estate,
Arcot Road, Porur, Chennai-600116
INDIA

Manufacturer Labeller Code : 71811

Consignee Labeller Code : 76168

Consignee:

Velocity Pharma LLC,
Farmingdale, NY 11735

Barcode

Label size : L-25cmxH-16cm

MAXIMUM STRENGTH LIDOCAINE PATCH

lidocaine patch

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:71811-001
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
LIDOCAINE (UNII: 98PI200987) (LIDOCAINE - UNII:98PI200987)	LIDOCAINE	40 mg

Inactive Ingredients

Ingredient Name	Strength
TARTARIC ACID (UNII: W4888I119H)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
CARBOXYMETHYLCELLULOSE SODIUM (UNII: K679OBS311)	
DIHYDROXYALUMINUM AMINOACETATE (UNII: DO250MG0W6)	
GLYCERIN (UNII: PDC6A3C0OX)	
EDETATE DISODIUM ANHYDROUS (UNII: 8NLQ36F6MM)	
METHYLPARABEN (UNII: A2I8C7HI9T)	

SODIUM POLYACRYLATE (2500000 MW) (UNII: 05I15JN12J)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
POLYVINYL ALCOHOL, UNSPECIFIED (UNII: 532B59J990)	
PROPYLPARABEN (UNII: Z8IX2SC1OH)	
WATER (UNII: 059QF0KO0R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:71811-001-05	500 in 1 BOX	09/24/2019	
1		5 in 1 CARTON; Type 0: Not a Combination Product		
2	NDC:71811-001-06	600 in 1 BOX	09/24/2019	
2		5 in 1 CARTON; 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	09/24/2019	

Labeler - Intermed (676244169)

Registrant - Velocity Pharma LLC (962198409)

Establishment

Name	Address	ID/FEI	Business Operations
Intermed		676244169	manufacture(71811-001)

Revised: 10/2021

Intermed