MAXIMUM STRENGTH LIDOCAINE PATCH- lidocaine patch
Velocity 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.

Maximum Strength Lidocaine Patch

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

Inactive Ingredients

aluminium hydroxide gel, bentonite, borax, carbomer, carboxymethylcellulose sodium, colloidal silicon dioxide, dihydroxyaluminumaminoacetate, disodiumedetate, gelatin, glycerin, oleic acid, polysorbate 80, polyvinyl Alcohol, potassium Sorbate, povidone, propylene glycol, sodiummetabisulphite, tartaric acid, trolamine, urea, water

Package/Label Principal Display Panel

MAX STRENGTH LIDOCAINE PATCH

-NUMBS AWAY PAIN

MAXIMUM STRENGTH LIDOCAINE PATCH

lidocaine patch

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:76168-067
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**
ALGELDRATE (UNII: 03J11K103C)	
BENTONITE (UNII: A3N5ZCN45C)	
CARBOMER 940 (UNII: 4Q93RCW27E)	
CARBOXYMETHYLCELLULOSE SODIUM (UNII: K679OBS311)	
DIHYDROXYALUMINUM AMINOACETATE (UNII: DO250MG0W6)	
EDETATE DISODIUM ANHYDROUS (UNII: 8NLQ36F6MM)	
GELATIN (UNII: 2G86QN327L)	
GLYCERIN (UNII: PDC6A3C0OX)	
OLEIC ACID (UNII: 2UMI9U37CP)	
POLYSORBATE 80 (UNII: 6OZP39ZG8H)	

POLYVINYL ALCOHOL, UNSPECIFIED (UNII: 532B59J990)	
POTASSIUM SORBATE (UNII: 1VPU26JZZ4)	
POVIDONE (UNII: FZ989GH94E)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
SODIUM METABISULFITE (UNII: 4VON5FNS3C)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
SODIUM BORATE (UNII: 91MBZ8H3QO)	
TROLAMINE (UNII: 9O3K93S3TK)	
TARTARIC ACID (UNII: W4888I119H)	
UREA (UNII: 8W8T17847W)	
WATER (UNII: 059QF0KO0R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:76168-067-11	5 in 1 CARTON	03/06/2017	
1		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	03/06/2017	

Labeler - Velocity Pharma LLC (962198409)

Registrant - Velocity Pharma LLC (962198409)

Revised: 3/2017 Velocity Pharma LLC