MAXIMUM STRENGTH LIDOCAINE PATCH- lidocaine patch
DR SABHARWAL'S WOUND CARE

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- RA bulk label

undefined

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

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Inactive Ingredients

Butylated hydroxyl toluene,cetostearyl alcohol,cetomacrogol 1000,cetyl alcohol,disodium EDTA,disodium hydrogen phosphate,light liquid paraffin,propylene glycol,sorbic acid,transquitol P, white petroleum jelly

Package Label

Odourless
Lidocaine Pain Relieving Patch

Active Ingredients:
Lidocaine 4% ..... Topical anesthetic

Batch No. : 7LP04 Mfg. Date : 2017/06 Exp. Date : 2019/05	Quantity : 1125 Patches Shipper No. : ____ of ____ Gross Wight : Net Weight :
STORE IN A COOL DRY PLACE. PROTECT FROM DIRECT SUNLIGHT / MOISTURE / FREEZING.	KEEP OUT OF REACH OF CHILDREN AND PETS. FOR EXTERNAL USE ONLY.
NDC No.: 76168-303-11	CONFORMANCE WITH THE F.D. & C ACT AND REGULATIONS THEREUNDER
Manufactured By: Dr. Sabharwal's Wound Care 137, Buranwala, Barotiwa-174103, HP, India Code: No. HP/Drugs/06/69	Manufacturer Labeler Code: 71318
Shipped To: VELOCITY PHARMA LLC 226/B SHERWOOD AVE, FARMINGDALE, NY-11735	0 11822 68614 3

MAXIMUM STRENGTH LIDOCAINE PATCH

lidocaine patch

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:71318-002
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**
BUTYLATED HYDROXYTOLUENE (UNII: 1P9D0Z171K)	
CETOSTEARYL ALCOHOL (UNII: 2DMT128M1S)	
CETYL ALCOHOL (UNII: 936JST6JCN)	
EDETATE DISODIUM ANHYDROUS (UNII: 8NLQ36F6MM)	
SODIUM PHOSPHATE, DIBASIC, ANHYDROUS (UNII: 22ADO53M6F)	
PARAFFIN (UNII: I9O0E3H2ZE)	

PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
SORBIC ACID (UNII: X045WJ989B)	
DIETHYLENE GLYCOL MONOETHYL ETHER (UNII: A1A1I8X02B)	
PETROLATUM (UNII: 4T6H12BN9U)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:71318-002-25	1125 in 1 CASE	06/22/2017	
1		1 in 1 PATCH; 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	06/22/2017	

Labeler - DR SABHARWAL'S WOUND CARE (862184668)

Registrant - Velocity Pharma LLC (962198409)

Establishment

Name	Address	ID/FEI	Business Operations
DR SABHARWAL'S WOUND CARE		862184668	manufacture(71318-002)

Revised: 6/2017 DR SABHARWAL'S WOUND CARE