

## **LIDOCAINE 4% GEL PATCH- lidocaine 4% gel patch 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.*

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Lidocaine 4%

Temporarily Relieves Minor Pain

Topical Anesthetic

For external use only

- More than one patch on your body at a time
- On cut, irritated swollen skin
- On puncture wounds
- For more than one week without consulting a doctor
- At the same time as other topical analgesics

Use only as directed.

Read and follow all directions and warnings on this label.

Rare case of serious burns have been reported with products of this type.

Do not apply to wounds or damaged, broken or irritated skin.

Do not allow contact with the eyes and mucous membranes.

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 analgesic.

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

A transient burning sensation may occur upon application but generally disappears in several days.

If a severe burning sensation occurs, discontinue use immediately.

Discontinue use at least 1 hour before a bath or shower.

Do not use immediately after a bath or shower.

### **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.

ask a health professional before use.

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

### **Adult and children over 12 years**

Clean and dry affected area.

Remove backing from patch by firmly grasping both ends and gently pulling until back separates in middle.

Carefully remove smaller portion of backing from the patch and apply exposed portion of patch to affected area.

Use 1 patch for up to 12 hours.

### Children 12 years or younger:

ask a doctor

Store at room temperature 20-25 °C (68-77 °F)

Alpha Tocopherol Acetate, Aluminium Glycinate, Aluminium Hydroxide, Aluminium Sulphate, Borax, Carbomer, Colloidal Silicon Dioxide, DMDM Hydantoin, Glycerine, Kaolin, Polyacrylic Acid, Polyvinyl Alcohol, Polyvinylpyrrolidone, Propylene Glycol, Purified Water, Sodium Carboxymethyl Cellulose, Sodium Ethylenediaminetetraacetic Acid, Sodium Polyacrylate, Sorbitol, Sorbitan Monooleate, Tartaric Acid & Titanium Dioxide.

Questions? Call 718-739-5680

Topical Patch for External Use Only

**LIDOCAINE 4% GEL PATCH**

Compare to active ingredient of Aspercreme® Maximum Strength Lidocaine Patch\*

NDC: 71318-112-15

## LIDOCAINE 4% Gel Patch



### Pain Relieving Patch

**MAXIMUM STRENGTH**

**TOPICAL ANESTHETIC**

**FAST ACTING**

**MAXIMUM STRENGTH**

for temporary relief of pain:

- Back
- Neck
- Shoulders
- Knee & Elbow

**15** Patches

3.94 in x 5.5 in (10cm x 14cm) EACH

Product Code: 4201

  
(011)89037420-42013  
885-4201 Rev. 00

**Applying your patch:**

- Gently remove smaller portion of backing from the middle of the patch.
- Apply exposed portion to affected area. Peel off the remaining backing layer and press the patch in place.



Drug Facts	Purpose
<b>Active Ingredient</b> Lidocaine 4%.....	Topical anesthetic
<b>Use</b> temporarily relieves minor pain	
<b>Warnings</b> For external use only	
<b>Do not use</b> ■ more than 1 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 ■ at the same time as other topical analgesics	
<b>When using this product:</b> ■ use only as directed. ■ read and follow all directions and warnings on this label ■ rare cases of serious burns have been reported with products of this type. ■ do not apply to wounds or damaged, broken or irritated skin ■ do not allow contact with the eyes and mucous membranes ■ 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 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. ■ a transient burning sensation may occur upon application but generally disappears in several days ■ if a severe burning sensation occurs, discontinue use immediately. ■ discontinue use at least 1 hour before a bath or shower. ■ do not use immediately after a bath or shower.	
<b>Stop use and ask a doctor if:</b> ■ condition worsens ■ redness is present ■ irritation develops ■ symptoms persist for more than 7 days or clear up and occur again	

**Directions**  
**Adult and children over 12 years:**  
■ Clean and dry affected area ■ remove backing from patch by firmly grasping both ends and gently pulling until back separates in middle  
■ Carefully remove smaller portion of backing from the patch and apply exposed portion of patch to affected area ■ use 1 patch for up to 12 hours

**Children 12 years or younger:** ask a doctor

**Other Information** store at room temperature 20-25°C (68-77°F)

**Inactive Ingredients** Alpha Tocopherol Acetate, Aluminium Glycinate, Aluminium Hydroxide, Aluminium Sulphate, Borax, Carbomer, Colloidal Silicon Dioxide, DMDM Hydantoin, Glycerine, Kaolin, Polyacrylic Acid, Polyvinyl Alcohol, Polyvinylpyrrolidone, Propylene Glycol, Purified Water, Sodium Carboxymethyl Cellulose, Sodium Ethylenediaminetetraacetic Acid, Sodium Polyacrylate, Sorbitol, Sorbitan Monooleate, Tartaric Acid & Titanium Dioxide.

**Questions? Call 718-739-5680**

Neutral Code No. HP/Drugs/MB/06/348  
\*This product is not manufactured or distributed by Chatterm, Inc., distributor of Aspercreme® Maximum Strength Lidocaine Patch.

**Child-Resistant Packaging**

Imported by **Ratvansa Inc** MADE IN INDIA  
106-15 Sutphin Blvd, Jamaica, NY 11435  
Exp. Date :  
Exp. Date :

## LIDOCAINE 4% GEL PATCH

# LIDOCAINE 4% GEL PATCH

lidocaine 4% gel patch patch

## Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:71318-112
<b>Route of Administration</b>	TOPICAL		

## Active Ingredient/Active Moiety

<b>Ingredient Name</b>	<b>Basis of Strength</b>	<b>Strength</b>
LIDOCAINE (UNII: 98PI200987) (LIDOCAINE - UNII:98PI200987)	LIDOCAINE	84 mg

## Inactive Ingredients

<b>Ingredient Name</b>	<b>Strength</b>
WATER (UNII: 059QF0KO0R)	
SORBITAN MONOOLEATE (UNII: 06XEA2VD56)	
POLYACRYLIC ACID (250000 MW) (UNII: 9G2MAD7J6W)	
DMDM HYDANTOIN (UNII: BYR0546TOW)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
SODIUM POLYACRYLATE (8000 MW) (UNII: 285CYO341L)	
GLYCERIN (UNII: PDC6A3C0OX)	
KAOLIN (UNII: 24H4NWX5CO)	
ALUMINUM HYDROXIDE (UNII: 5QB0T2IU0)	
CARBOMER 940 (UNII: 4Q93RCW27E)	
POLYVINYL ALCOHOL (100000 MW) (UNII: 949E52Z6MY)	
SORBITOL (UNII: 506T60A25R)	
ALPHA-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
TARTARIC ACID (UNII: W4888I119H)	

## Product Characteristics

<b>Color</b>	white	<b>Score</b>	
<b>Shape</b>	RECTANGLE	<b>Size</b>	
<b>Flavor</b>		<b>Imprint Code</b>	
<b>Contains</b>			

## Packaging

<b>#</b>	<b>Item Code</b>	<b>Package Description</b>	<b>Marketing Start Date</b>	<b>Marketing End Date</b>
1	NDC:71318-112-15	15 in 1 CARTON	08/10/2023	
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	08/10/2023	

**Labeler** - Dr. Sabharwal's Wound Care (862184668)

**Registrant** - Dr. Sabharwal's Wound Care (862184668)

## Establishment

Name	Address	ID/FEI	Business Operations
Dr. Sabharwal's Wound Care		862184668	manufacture(71318-112)

Revised: 8/2023

Dr. Sabharwal's Wound Care