

**DR SABHARWALS- lidocaine 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.

Call +91-905-677-0088

Topical Patch for External Use Only

## Dr Sabharwal's<sup>®</sup>

### Lidocaine 4% Gel Patch



**MAXIMUM STRENGTH**

for temporary relief of pain:

- Back
- Neck
- Shoulders
- Knee & Elbow

### Pain Relieving Patch


**MAXIMUM STRENGTH**

**TOPICAL ANESTHETIC**

**FAST ACTING**

Quantity: 1 N Patch of Size 7cm x 10cm, Individually Packed

Product Code: 4202



(018)903762042023  
885-4202 New, 03

Front

Package / Inner Pouch

<p><b>Drug Facts</b></p> <p><b>Active Ingredient</b> Lidocaine 4%</p> <p><b>Purpose</b> Topical anesthetic</p> <p><b>Use</b> Temporarily relieves minor pain</p> <p><b>Warnings</b> For external use only</p> <p><b>Do not use</b> 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.</p> <p><b>When using this product</b> Use only as directed. Read and follow all directions and warnings on this label. Use 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 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.</p> <p>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.</p> <p><b>Do not use</b> immediately after a bath or shower.</p> <p><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 within a few days. You experience signs of skin injury, such as pain, swelling or blistering where the product was applied.</p>	<p>■ If pregnant or breast feeding, ask a health professional before use.</p> <p>■ Keep out of reach of children and pets. If swallowed, get medical help or contact a Poison Control Center right away.</p> <p><b>Directions</b></p> <p><b>Adult and children over 12 years</b></p> <p>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.</p> <p><b>Children 12 years or younger:</b> ask a doctor</p> <p><b>Other information:</b> Store at room temperature 20-25°C (68-77°F)</p> <p><b>Inactive ingredients:</b> 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 &amp; Titanium Dioxide.</p> <p><b>Questions? Call +91-905-677-0088</b></p> <p>Mfd. In India by: <b>Dr. Sabharwal's Wound Care</b> 137 Baramulla, Barrowalla (H.P.), India - 174 103 Manager QA, Customer Care Call Telephone: +91 1722640018 Cell: +91 90567 70088 E-mail: buyers@drsabharwal.in</p>
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Back

**DR SABHARWALS**

lidocaine gel patch patch

## Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:71318-111
<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>
ALPHA-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
SODIUM POLYACRYLATE (8000 MW) (UNII: 285CYO341L)	
SORBITAN MONOOLEATE (UNII: 06XEA2VD56)	
POLYACRYLIC ACID (250000 MW) (UNII: 9G2MAD7J6W)	
CARBOMER 940 (UNII: 4Q93RCW27E)	
ALUMINUM HYDROXIDE (UNII: 5QB0T2IUN0)	
GLYCERIN (UNII: PDC6A3C0OX)	
KAOLIN (UNII: 24H4NWX5CO)	
POLYVINYL ALCOHOL (100000 MW) (UNII: 949E52Z6MY)	
TARTARIC ACID (UNII: W4888I119H)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
WATER (UNII: 059QF0KO0R)	
SORBITOL (UNII: 506T60A25R)	
DMDM HYDANTOIN (UNII: BYR0546TOW)	

## 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

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:71318-111-15	15 in 1 CARTON	03/27/2023	
1		1 in 1 POUCH; Type 0: Not a Combination Product		

## Marketing Information

Marketing	Application Number or Monograph	Marketing Start	Marketing End
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Category	Citation	Date	Date
OTC monograph not final	part348	03/27/2023	

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

**Registrant** - Dr Sabharwals Wound Care (862184668)

### Establishment

Name	Address	ID/FEI	Business Operations
Dr. Sabharwal's Wound Care		862184668	manufacture(71318-111)

Revised: 3/2023

Dr. Sabharwal's Wound Care