

## **LIDOCAINE- lidocaine patch**

**Kroger Company**

*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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### **Kroger Co. Lidocaine Patch Drug Facts**

#### **Active ingredient**

Lidocaine 4%

#### **Purpose**

Topical anesthetic

#### **Uses**

For temporary relief of pain

#### **Warnings**

**For external use only**

#### **Do not use**

- more than 1 patch at a time
- on wounds or damaged skin
- with a heating pad
- if you have ever had an allergic reaction to this product or any of its ingredients

#### **When using this product**

- use only as directed
- avoid contact with the eyes, mucous membranes or rashes
- do not bandage tightly

#### **Stop use and ask a doctor if**

- localized skin reactions occur, such as rash, itching, redness, irritation, pain, swelling and blistering
- conditions worsen
- symptoms persist for more than 7 days
- symptoms clear up and occur again within a few days

#### **If pregnant or breast-feeding,**

ask a health professional before use.

**Keep out of reach of children.**

If swallowed, get medical help or contact a Poison Control Center right away (1-800-222-1222).

**Directions****Adults and children 12 years of age and over:**

- clean and dry affected area
- remove film from patch and apply to the skin (see illustration)
- apply 1 patch at a time to affected area, not more than 3 to 4 times daily
- remove patch from the skin after at most 8 hours of application

**Children under 12 years of age:** consult a doctor

**Other information**

- avoid storing product in direct sunlight
- protect product from excessive moisture
- store at 20-25°C (68-77°F)

**Inactive ingredients**

carboxymethylcellulose sodium, dihydroxyaluminum aminoacetate, edetate disodium, glycerin, kaolin, methylparaben, polyacrylic acid, polyvinyl alcohol, propylene glycol, propylparaben, purified water, sodium polyacrylate, sodium polyacrylate starch, sorbitol solution, tartaric acid, urea

**Questions or comments?**

**1-800-632-6900**

**Package/Label Principal Display Panel**

COMPARE TO the active ingredient of SALONPAS® LIDOCAINE PATCH See back panel.

Maximum Strength

Lidocaine Patch

4% Lidocaine/Topical Anesthetic

For Back, Neck, Knees, Shoulders & Elbows

Up to 8 Hours of Relief

For Temporary Relief of Pain

Desensitize Aggravated Nerves

Numbing Relief

Unscented

6 PATCHES

3 15/16 IN X 5 ½ IN (10cm x 14cm)



## LIDOCAINE

lidocaine patch

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:30 142-697
<b>Route of Administration</b>	TOPICAL, PERCUTANEOUS, TRANSDERMAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
LIDOCAINE (UNII: 98PI200987) (LIDOCAINE - UNII:98PI200987)	LIDOCAINE	4 mg

### Inactive Ingredients

Ingredient Name	Strength
CARBOXYMETHYLCELLULOSE SODIUM (UNII: K679OBS311)	
DIHYDROXYALUMINUM AMINOACETATE (UNII: DO250MG0W6)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	
GLYCERIN (UNII: PDC6A3C0OX)	
KAOLIN (UNII: 24H4NWX5CO)	
METHYLPARABEN (UNII: A2I8C7HI9T)	
POLYVINYL ALCOHOL (UNII: 532B59J990)	

<b>PROPYLENE GLYCOL</b> (UNII: 6DC9Q167V3)	
<b>PROPYLPARABEN</b> (UNII: Z8IX2SC1OH)	
<b>WATER</b> (UNII: 059QF0K00R)	
<b>SORBITOL</b> (UNII: 506T60A25R)	
<b>TARTARIC ACID</b> (UNII: W4888119H)	
<b>UREA</b> (UNII: 8W8T17847W)	

<b>Packaging</b>				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:30 142-697-91	6 in 1 CARTON	05/17/2019	
1		1 in 1 POUCH; Type 0: Not a Combination Product		

<b>Marketing Information</b>			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part348	05/17/2019	

**Labeler** - Kroger Company (006999528)