SALONPAS LIDOCAINE PAIN RELIEVING- lidocaine patch
Hisamitsu Pharmaceutical Co., Inc.

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.

Active ingredient

Lidocaine 4%

Purpose

Topical anesthetic

Uses

For temporary relief of pain

Warnings

For external use only

Do not use

- more than one patch at a time
- on wounds or damaged skin
- with a heating pad
- if you are allergic to any igredients of this product

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, irritaion, 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.

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 to affected are not more than 3 to 4 times daily
- remove patch from the skin after at most 8-hour application

Children under 12 years of age: consult a doctor

Other information
- Avoid storing product in direct sunlight
- Protect product from excessive moisture

Inactive ingredients

aluminum silicate, dihydroxyaluminum aminoacetate, disodium edetate, gelatin, glycerin, methylparaben, oleic acid, polyacrylic acid, polyvinyl alcohol, propylene glycol, propylparaben, sodium polyacrylate, tartaric acid, titanium dioxide, water

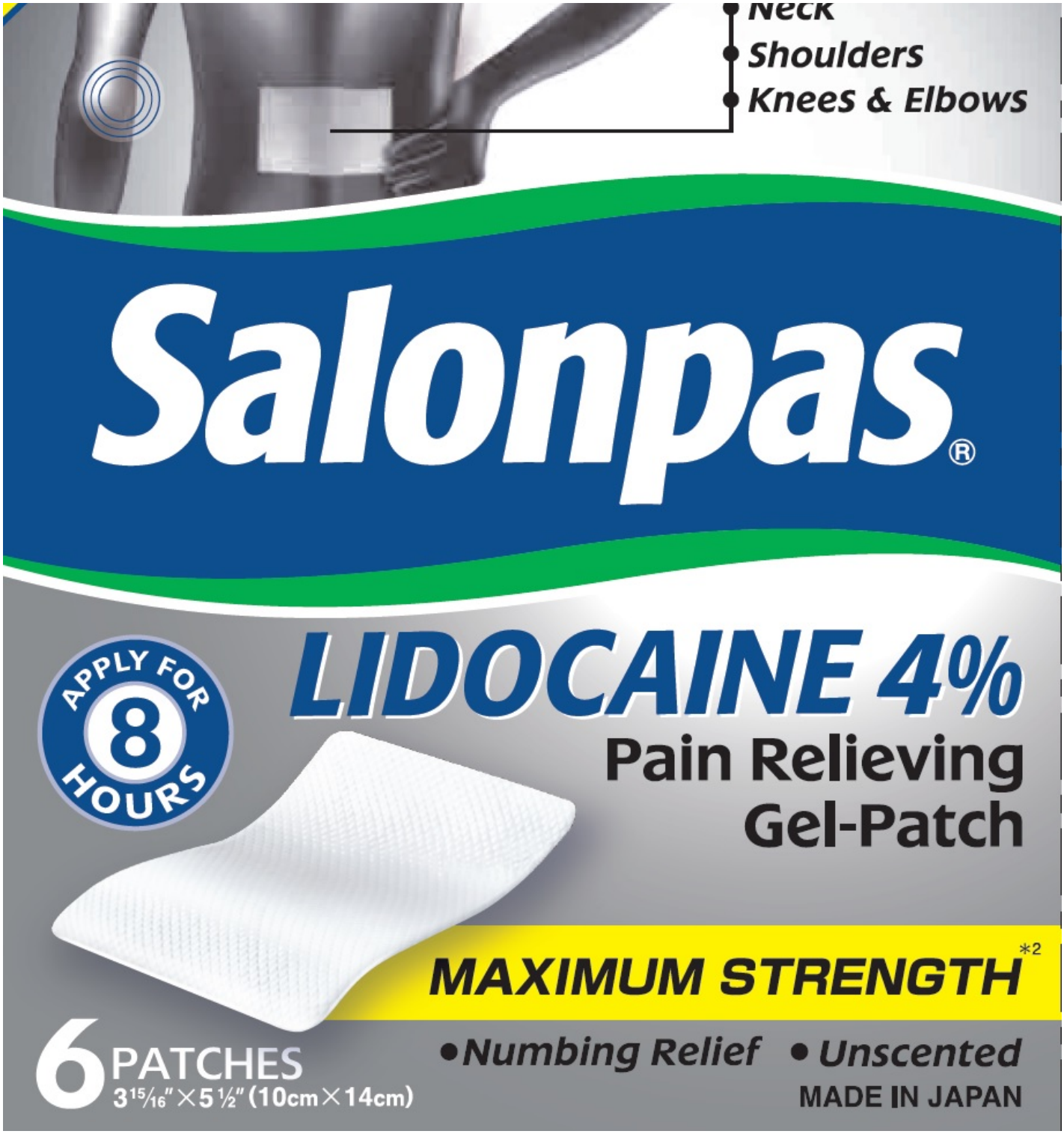
Questions or comments?

Toll free **1-800-826-8861** www.salonpas.us

Principal Display Panel

IMPROVED ADHESION*1
Hisamitsu
NDC#46581-830-06
Desensitize aggravated nerves
for temporary relief of pain
- Back
- Neck
- Shoulders
- Knees and Elbows

Salonpas LIDOCAINE 4% Pain Relieving Gel-Patch
APPLY FOR 8 HOURS
MAXIMUM STRENGTH*2
Numbing Relief
Unscented
6 PATCHES
3 15/16" X 5 1/2" (10cm X 14cm)
MADE IN JAPAN



Principal Display Panel

CUT OPEN HERE

NDC#46581-830-01

HOW TO APPLY
1 Pull apart.
2 Peel off one side of the film.
3 Place on affected area.
4 Peel off the remaining film.
5 Press patch thoroughly.

Salonpas LIDOCAINE 4% Pain Relieving Gel-Patch

APPLY FOR 8 HOURS

MAXIMUM STRENGTH*1
Numbing Relief
Unscented

1 PATCH
3 15/16" X 5 1/2" (10cm X 14cm)

Child-resistant packaging.

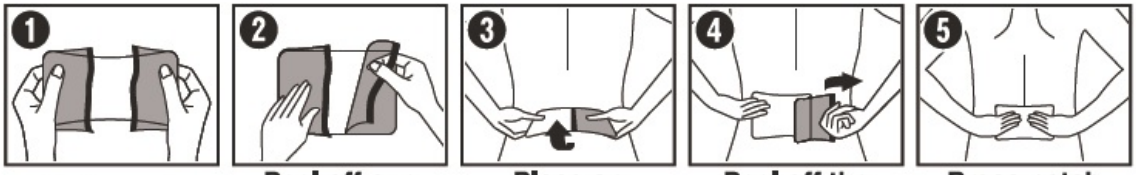
Hisamitsu

MADE IN JAPAN

CUT OPEN HERE - CUT OPEN HERE

NDC#46581-830-01

HOW TO APPLY



1. Pull apart.
2. Peel off one side of the film.
3. Place on affected area.
4. Peel off the remaining film.
5. Press patch thoroughly.

Salonpas®

APPLY FOR 8 HOURS

LIDOCAINE 4%

Pain Relieving Gel-Patch

MAXIMUM STRENGTH[*1]

- Numbing Relief
- Unscented

1 PATCH
3 15/16" × 5 1/2" (10cm × 14cm)

Child-resistant packaging.

Hisamitsu®

MADE IN JAPAN

N 46581-830-01 9

SALONPAS LIDOCAINE PAIN RELIEVING

lidocaine patch

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:46581-830
Route of Administration	TOPICAL, PERCUTANEOUS, TRANSDERMAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
LIDOCAINE (UNII: 98PI200987) (LIDOCAINE - UNII:98PI200987)	LIDOCAINE	560 mg

Inactive Ingredients	
Ingredient Name	**Strength**
ALUMINUM SILICATE (UNII: T1FAD4SS2M)	
DIHYDROXYALUMINUM AMINOACETATE (UNII: DO250MG0W6)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	
GELATIN (UNII: 2G86QN327L)	
GLYCERIN (UNII: PDC6A3C0OX)	
METHYLPARABEN (UNII: A2I8C7HI9T)	
OLEIC ACID (UNII: 2UMI9U37CP)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
PROPYLPARABEN (UNII: Z8IX2SC1OH)	
TARTARIC ACID (UNII: W4888I119H)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
WATER (UNII: 059QF0KO0R)	

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:46581-830-06	6 in 1 BOX	08/01/2016	
1		1 in 1 POUCH; Type 0: Not a Combination Product		
2	NDC:46581-830-02	2 in 1 BOX	10/01/2017	
2		1 in 1 POUCH; Type 0: Not a Combination Product		
3	NDC:46581-830-15	15 in 1 BOX	08/01/2017	
3		1 in 1 POUCH; Type 0: Not a Combination Product		
4	NDC:46581-830-01	1 in 1 POUCH; Type 0: Not a Combination Product	08/01/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part348	08/01/2016	

Labeler - Hisamitsu Pharmaceutical Co., Inc. (690539713)