

ASPERCREME LIDOCAINE XL- lidocaine patch
Lead Chemical Co., Ltd.

Aspercreme Lidocaine XL Patch

Active ingredient

Lidocaine 4%

Purpose

Topical anesthetic

Use

for the temporary relief of pain

Warnings

For external use only

Do not use

- on puncture wounds, cuts, irritated or swollen skin
- more than 1 patch on your body at a time or with other topical analgesics at the same time
- with a heating pad or apply local heat to the area of use

When using this product

- use only as directed
- do not bandage tightly
- avoid contact with the eyes
- 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.

Stop use and ask a doctor if

- condition worsens or symptoms persist for more than 7 days
- symptoms clear up and occur again within a few days
- redness or irritation develops
- 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 12 years of age and older:

- 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 at a time and not more than 3 to 4 times daily

children 12 years or younger: consult a doctor

Inactive ingredients

aluminum glycinat e, aluminum hydroxide, cellulose gum, glycerin, methyl acrylate/2-ethylhexyl acrylate copolymer, methylparaben, nonoxynol-30, polyacrylic acid, polysorbate 80, propylene glycol, silica, sodium polyacrylate, tartaric acid, titanium dioxide, urea, water

Package/Label Principal Display Panel

MAX STRENGTH

Aspercreme®
with 4% LIDOCAINE
PAIN RELIEF PATCH

NUMBS AWAY PAIN
FAST ACTING
TARGETS NERVES
FLEXIBLE FABRIC

#1 LIDOCAINE BRAND*

XL PATCH
71% LARGER†

FRAGRANCE-FREE

Contains 1 Patch 4-¾" x 7-7/8" (12 cm x 20 cm)
Pain Relieving Ointment on a Breathable Adhesive Pad

*Among OTC topical analgesics.

†Than 10 cm x 14 cm Aspercreme® patches.

CHATTEM®
A SANOFI COMPANY
Dist. By Chattem, Inc., a Sanofi Company
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www.aspercreme.com Made in Japan



The image shows the packaging for Aspercreme Lidocaine XL Patch. The top of the box features the text "MAX STRENGTH" in a blue, sans-serif font. Below this is the brand name "Aspercreme®" in a large, bold, blue script font. Underneath the brand name is a blue banner with the word "LIDOCAINE" in white, bold, sans-serif capital letters. To the left of "LIDOCAINE" is the text "WITH 4%". Below the banner is the text "PAIN RELIEF PATCH" in blue, sans-serif capital letters. On the right side of the box is a circular seal with a scalloped edge, containing the text "#1 LIDOCAINE BRAND*" in white. On the left side, there are four lines of text: "NUMBS AWAY PAIN", "FAST ACTING", "TARGETS NERVES", and "FLEXIBLE FABRIC", all in blue, sans-serif capital letters. In the center-right, there is a blue circular graphic showing a human torso with a white patch on the lower back. To the left of this graphic is a blue banner with the text "XL PATCH" in white, bold, sans-serif capital letters, and "71% LARGER†" in white, sans-serif capital letters below it. At the bottom left, there is text: "FRAGRANCE-FREE", "Contains 1 Patch 4-3/4" x 7-7/8" (12 cm x 20 cm)", and "Pain Relieving Ointment on a Breathable Adhesive Pad", all in blue, sans-serif capital letters. At the bottom right, there is small text: "*Among OTC topical analgesics." and "† Than 10 cm x 14 cm Aspercreme® patches."

Label

ASPERCREME LIDOCAINE XL

lidocaine patch

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:62168-0585
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
LIDOCAINE (UNII: 98PI200987) (LIDOCAINE - UNII:98PI200987)	LIDOCAINE	411.4 mg

Inactive Ingredients

Ingredient Name	Strength
DIHYDROXYALUMINUM AMINOACETATE ANHYDROUS (UNII: 1K713C615K)	
ALUMINUM HYDROXIDE (UNII: 5QB0T2IUN0)	
CARBOXYMETHYLCELLULOSE SODIUM, UNSPECIFIED FORM (UNII: K679OBS311)	
GLYCERIN (UNII: PDC6A3C0OX)	
METHYLPARABEN (UNII: A2I8C7HI9T)	
NONOXYNOL-30 (UNII: JJX07DG188)	
POLYSORBATE 80 (UNII: 6OZP39ZG8H)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
TARTARIC ACID (UNII: W4888I119H)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
UREA (UNII: 8W8T17847W)	
WATER (UNII: 059QF0KOOR)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:62168-0585-2	240 in 1 CARTON	05/28/2021	
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 Drug	505G(a)(3)	10/15/2017	

Labeler - Lead Chemical Co., Ltd. (693727091)