LIDOCAINE 4% MAXIMUM OTC STRENGTH- lidocaine patch Cardinal Health 107, LLC

Lidocaine Maximum OTC Strength Patch 4%

Active Ingredient

Lidocaine 4.0%

Purpose

Topical anesthetic

Indications and Usage

Temporarily relieves minor pain.

Warnings

For external use only.

Do not use

- More than one 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
- If you are allergic to any active or inactive ingredients
- If pouch is damaged or opened.

When using this product

- Use only as directed
- Read and follow all directions and warnings on this carton
- Do not allow contact with the eyes
- Do not use at the same time as other topical analgesics
- Do not bandage tightly or apply local heat (such as heating pads) to the area of use
- Do not microwave
- 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 consult a doctor

- 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.

If pregnant or breastfeeding,

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 800-222-1222 right away.

Directions

Directions Adults and children 12 years of age and over: Clean and dry affected area, free of lotions, ointments and creams. Carefully remove backing from patch starting at a corner. Apply sticky side of patch to affected area. Do not more than use one patch in a 12 hour period. Maximum 2 patches per day. Discard patch after single use. Children under 12 years of age: consult a physician.

Other information

Store in a clean, dry place outside of direct sunlight. Protect from excessive moisture.

Inactive Ingredients

aluminum glycinate, glycerin, kaolin, methylparaben, polyacrylic acid, polysorbate 80, propylene glycol, propylparaben, PVP, sodium polyacrylate, tartaric acid, titanium dioxide, water

Questions or comments

Call 1-866-326-1313

This product is not manufactured or distributed by Chattem Inc., owner of the registered trademark Aspercreme®.

Distributed by:

RUGBY® LABORATORIES

Indianapolis, IN 46268

Distributed By:

Cardinal Health

Dublin, OH 43017

Made in China

Questions or comments?

Call 1-800-616-2471

www.majorpharmaceuticals.com

Principal Display Panel

LIDOCAINE PATCH 4%
MAXIMUM OTC STRENGTH
5 PATCHES



M122

NDC 55154-7813-5

LIDOCAINE PATCH 4% MAXIMUM OTC STRENGTH

5 PATCHES

Pain Relief

Lidocaine Topical Anesthetic

Desensitizes aggravated nerves and relieves pain

Compare to the active ingredient in Aspercreme® Maximum

Strength Lidocaine Patch++

Unscented formula Single-use patch Flexible adhesive patch

Drug Facts

Active Ingredient

Purpose

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Topical anesthetic

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Polyacrylic Acid, Polysorbate 80, Propylene Glycol, Propylparaben, PVP, Sodium Polyacrylate, Tartaric Acid, Titanium Dioxide, Water

Use Temporarily relieves minor pain.

Directions

Adults and children 12 years of age and over: Clean and dry affected area, free of lotions, ointments and creams. Carefully remove backing from patch starting at a corner. Apply sticky side of patch to affected area.

Do not use more than one patch in a 12 hour period.

Maximum 2 patches per day. Discard patch after single use.

Children under 12 years of age: consult a physician.

STORAGE: Store in a clean, dry place outside of direct sunlight.

Protect from excessive moisture.

WARNINGS:

For external use only

WARNING: This Unit Dose package is not child resistant and is Intended for Institutional Use Only. Keep this and all drugs out of

the reach of children.

If pregnant or breastfeeding, 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 800-222-1222 right away.

Questions or comments? Call 1-866-326-1313

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Distributed by Cardinal Health

Dublin, 0H 43017 L59206240624

Lot: Exp:

LIDOCAINE 4% MAXIMUM OTC STRENGTH

lidocaine patch

Product	Inform	ation
Product	intorm	ation

Product Type HUMAN OTC DRUG Item Code (Source) NDC:55154-7813(NDC:0536-1202)

Route of Administration TOPICAL

Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
LIDOCAINE (UNII: 98PI200987) (LIDOCAINE - UNII:98PI200987)	LIDOCAINE	4 g in 100 g	

Inactive Ingredients		
Ingredient Name	Strength	
ALUMINUM (UNII: CPD4NFA903)		
GLYCERIN (UNII: PDC6A3C0OX)		
KAOLIN (UNII: 24H4NWX5CO)		
METHYLPARABEN (UNII: A2I8C7HI9T)		
POLYACRYLIC ACID (300000 MW) (UNII: A8371R0U5J)		
POLYSORBATE 80 (UNII: 60ZP39ZG8H)		
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)		
PROPYLPARABEN (UNII: Z8IX2SC1OH)		
POVIDONE, UNSPECIFIED (UNII: FZ989GH94E)		
SODIUM POLYACRYLATE (2500000 MW) (UNII: 05I15JNI2J)		
TARTARIC ACID (UNII: W4888I119H)		
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)		
WATER (UNII: 059QF0KO0R)		

Product Characteristics			
Color		Score	
Shape	RECTANGLE	Size	
Flavor		Imprint Code	
Contains			

P	Packaging			
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:55154- 7813-5	5 in 1 BAG	06/20/2024	
1		9 g in 1 PATCH; Type 0: Not a Combination Product		

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M017	04/01/2019	

Labeler - Cardinal Health 107, LLC (118546603)

Revised: 6/2024 Cardinal Health 107, LLC