

LIDOCAINE 4%- lidocaine 4% patch
Marcella Health

ACTIVE INGREDIENTS

Lidocaine 4% w/w

OTHER INGREDIENTS

Dihydroxyaluminum Aminoacetate, Edetate Disodium, Glycerin, Kaolin, Methylparaben, Polysorbate 80, Propylene Glycol, Polyacrylic Acid, Polyvinylpyrrolidone K90, Propylparaben, Sodium Polyacrylate, Tartaric Acid, Titanium Dioxide, Water.

PURPOSE & USE

External Anesthetic - For temporary relief of pain

WARNINGS

For external use only.

Dosage & Administration

Adults and Children 12 Years of Age or Over:

- Apply one 4% lidocaine patch at a time to the affected area.
- Use up to 3 times daily, with each application lasting no more than 8 hours.
- Clean and dry the skin before applying the patch.
- Remove the patch after the specified duration and reseal the pouch containing unused patches.

Children Under 12 Years of Age: Consult a doctor for use.

Precautions:

- Avoid applying to broken or irritated skin.
- Do not apply more than one patch at a time.
- Avoid using local heat sources on the area where the patch is applied.

DO NOT USE

Do not use:

- on the face or rashes, on wounds or damaged skin
- in the eyes, mouth, or other mucous membranes
- on genitals
- with a heating pad
- right before or after heart surgery
- any patch from a pouch that has been opened for 7 or more days

- in large quantities, particularly over raw surfaces or blistered areas
- if tamper-evident seal is torn, broken, or missing
- more than 2 patches per day unless directed by a doctor
- **children under 18 years of age**

Ask a doctor before use if you have:

- allergies to topical products
- high blood pressure, heart disease, or kidney disease

When using this product, avoid contact with eyes. If eye contact occurs, rinse thoroughly with water.

The risk of heart attack or stroke may increase if you use more than directed or for longer than directed.

Stop use and ask doctor if condition worsens, or if symptoms persist for more than 7 days or clear up and occur again within a few days.

If pregnant or breast-feeding, ask a health professional before use

Do not use during last 3 months of pregnancy because it may cause problems in the unborn child or complications during delivery.

Keep out of reach of children.

If put in mouth, seek medical help or contact a Poison Control Center right away.

Dispose of the used patches by folding sticky ends together.

Uses:

For temporary relief of pain

WHEN USING THIS PRODUCT

- Use only as directed
- Avoid contact with the eyes, mucous membranes or rashes
- Do not bandage

STOP USE ... 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

CONSULT WITH A DOCTOR OR PHARMACIST BEFORE CONTINUED USE IF

- Localized skin reactions occur, such as rash, itching, redness, irritation, pain, swelling and blistering

- Conditions worsen
- Symptoms persists for more than 7 days
- Symptoms clear up and occur again within a few days

IF YOU ARE PREGNANT OR BREAST-FEEDING

ALWAYS FIRST CONSULT WITH A HEALTH PROFESSIONAL

KEEP OUT OF THE REACH OF CHILDREN

If swallowed, get medical help or contact a Poison Control Center right away.

OTHER INFORMATION


- Some individuals may not experience pain relief until several minutes or hours after applying the patch
- Avoid storing product in direct sunlight
- Protect product from excessive moisture

QUESTIONS?

Call toll-free: (307) 410-3813 or Email: info@marcellahealth.com


85096-201-01

85096-201-01: 1 patch in 1 pouch:



The image shows the packaging for the Lidocaine Patch. It is a dark blue pouch with the Marcella Health logo at the top left. The text "Lidocaine Patch" is prominently displayed in white. Below it, "Lidocaine 4% Pain Relieving Patch" is written in blue. At the bottom, it says "1 PATCH" and "5.5 x 3.9 in (14 x 10cm)". A vertical dimension line on the right side of the pouch indicates a height of 5mm.

DRUG FACTS	
Active Ingredients (in each patch): Lidocaine 4%	Purpose External 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 are allergic to any ingredients 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, 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	
DIRECTIONS: Adults and children 12 years and over: • Clean and dry affected area • Remove film from patch and apply to the skin • 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-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: Dihydroxyaluminum Aminoacetate, Edetate Disodium, Glycerin, Kaolin, Methylparaben, Polysorbate 80, Propylene Glycol, Polyacrylic Acid, Polyvinylpyrrolidone K90, Propylparaben, Sodium Polyacrylate, Tartaric Acid, Titanium Dioxide, Water.	
Questions or Comments: Call toll-free (307) 410-3813 or info@marcellahealth.com	

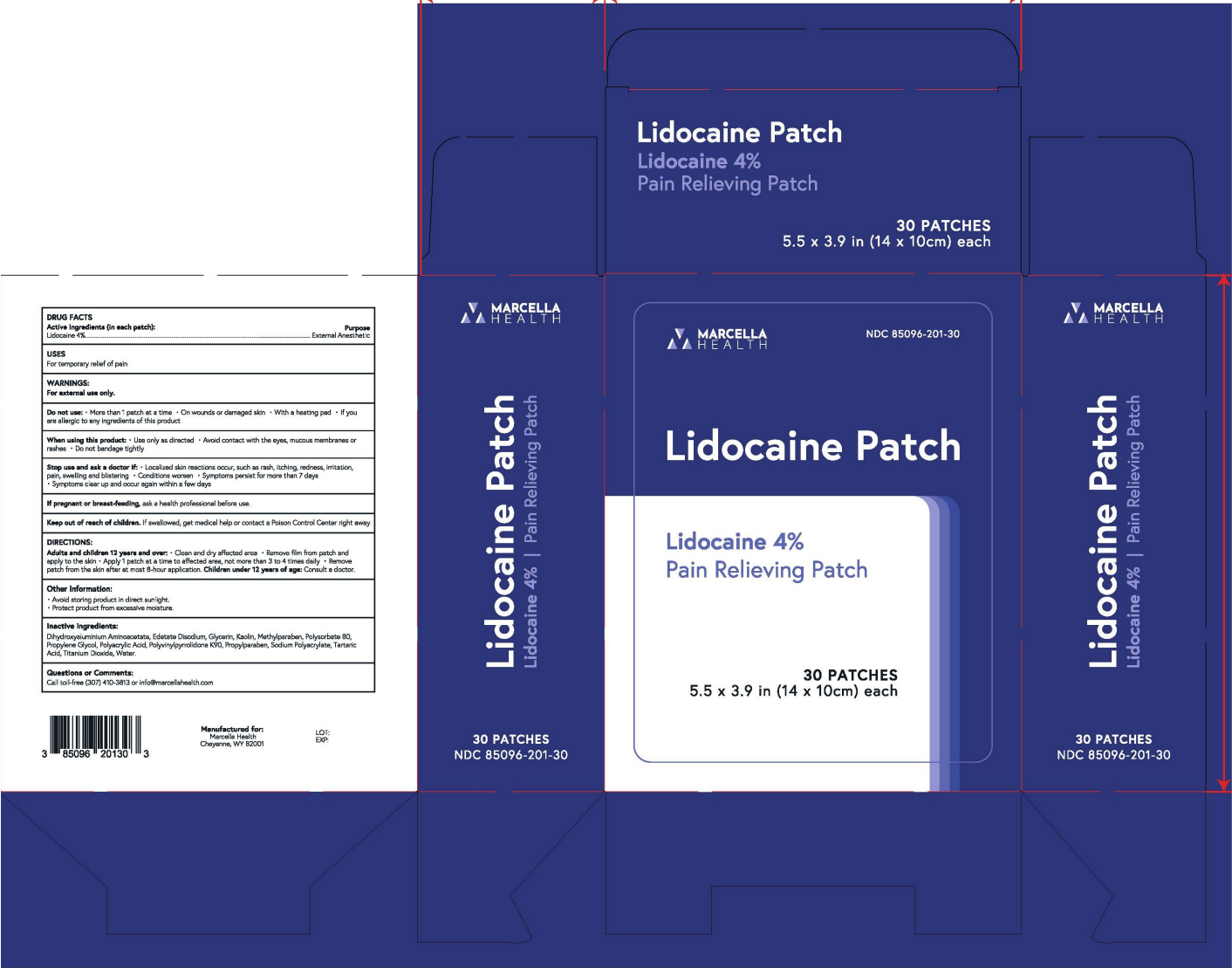


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Manufactured for:
Marcella Health
Cheyenne, WY 82001

LOT:
EXP:

85096-201-30



LIDOCAINE 4%

lidocaine 4% patch

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:85096-201
Route of Administration	TRANSDERMAL		
Active Ingredient/Active Moiety			
Ingredient Name		Basis of Strength	Strength
LIDOCAINE (UNII: 98PI200987) (LIDOCAINE - UNII:98PI200987)		LIDOCAINE	400 mg in 10 g
Inactive Ingredients			
Ingredient Name			Strength

TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
GLYCERIN (UNII: PDC6A3C0OX)	
POVIDONE K90 (UNII: RDH86HJV5Z)	
KAOLIN (UNII: 24H4NWX5CO)	
TARTARIC ACID (UNII: W4888I119H)	
SODIUM POLYACRYLATE (2500000 MW) (UNII: 05I15JNI2J)	
DIHYDROXYALUMINUM AMINOACETATE ANHYDROUS (UNII: 1K713C615K)	
METHYLPARABEN (UNII: A2I8C7HI9T)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	
POLYSORBATE 80 (UNII: 6OZP39ZG8H)	
HYDROXYACETOPHENONE (UNII: G1L3HT4CMH)	
PROPYLPARABEN (UNII: Z8IX2SC1OH)	
WATER (UNII: 059QF0KO0R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:85096-201-30	30 in 1 BOX	03/14/2025	
1	NDC:85096-201-01	10 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	03/14/2025	

Labeler - Marcella Health (119381899)

Revised: 3/2025

Marcella Health