

LIDOGUARD- lidocaine 4% patch
ViolaCare, Inc.

LidoGuard™ Pain Relief Patch
Lidocaine 4% External Analgesic

Pain Relieving Gel Patch
For Temporarily Relieves Minor Pain

Drug Facts

Active Ingredients

Lidocaine 4%

Purpose

External Anesthetic

Uses:

Temporarily relieves minor pain

Warnings:

For external use only

Do not use

- More than 1 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
- At the same time as other topical analgesics

When using the product

- Use only as directed
- Read and follow all directions and warnings on this label
- Rare cases of serious burns have been reported with products of this type
- Do not apply to wounds or damaged, broken, or irritated skin
- Do not allow contact with the eyes and mucous membranes
- Do not bandage tightly or apply local heat (such as heating pads) to the area of use
- Do not use at the same time as other topical analgesics
- Dispose of used patch in a manner that always keeps the 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
- A transient burning sensation may occur upon application but generally disappears in

several days

- If a severe burning sensation occurs, discontinue use immediately
- Discontinue use at least 1 hour before a bath or shower
- Do not use immediately use after a bath or shower

Stop use and ask doctor if

- Your condition worsens
- Redness is present
- Irritation develops
- Symptoms persist for more than 7 days or a 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

Pregnancy or breast feeding section

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

Adult and children over 12 years:

- Clean and dry affected area
- Remove backing from patch by firmly grasping both ends and gently pulling until back separates in the middle
- Carefully remove smaller portion of backing from the patch and apply exposed portion of patch to affected area
- Use 1 patch for up to 12 hours

Children 12 years or younger:Ask a doctor

Other information:

Store at room temperature 20° - 25°C (68°-77°F)

Inactive Ingredients: Alpha Tocopherol Acetate, Aluminum Glycinate, Aluminum Hydroxide, Aluminum Sulphate, Borax, Carbomer, Colloidal Silicon Dioxide, DMDM Hydantoin, Glycerin, Kaolin, Polyacrylic Acid, Polyvinyl Alcohol, Polyvinylpyrrolidone, Propylene Glycol, Purified Water, Sodium Carboxymethyl Cellulose, Sodium Propylene Glycol, Sodium Polyacrylate, Sorbitol, Sorbitan Monooleate, Tartric Acid & Titanium Dioxide

Question Section

Questions? Call 877-227-3137

PRINCIPAL DISPLAY PANEL



NDC 85231-100-15

LidoGuard Pain Relief Patch

Pain Relieving Gel Patch

12hr Fast Acting Relief

Maximum Strength

15 Patches - Pain Relieving Gel Patch

15 Patches

3.94 in x 5.5 in EACH

Packaged For:

ViolaCare Inc.

Parsippany, New Jersey, 07054

LIDOGUARD

lidocaine 4% patch

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:85231-100
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
LIDOCAINE HYDROCHLORIDE (UNII: V13007Z41A) (LIDOCAINE - UNII:98PI200987)	LIDOCAINE HYDROCHLORIDE ANHYDROUS	4 g in 100 g

Inactive Ingredients

Ingredient Name	Strength
ALPHA-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
ALUMINUM HYDROXIDE (UNII: 5QB0T2IUN0)	
CARBOMER 940 (UNII: 4Q93RCW27E)	
DMDM HYDANTOIN (UNII: BYR0546TOW)	
GLYCERIN (UNII: PDC6A3C0OX)	
KAOLIN (UNII: 24H4NWX5CO)	
POLYACRYLIC ACID (250000 MW) (UNII: 9G2MAD7J6W)	
POLYVINYL ALCOHOL (100000 MW) (UNII: 949E52Z6MY)	
WATER (UNII: 059QF0KO0R)	
SODIUM POLYACRYLATE (8000 MW) (UNII: 285CYO341L)	
SORBITOL (UNII: 506T60A25R)	
SORBITAN MONOOLEATE (UNII: 06XEA2VD56)	
TARTARIC ACID (UNII: W4888I119H)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:85231-100-15	15 in 1 BOX	05/01/2025	
1		1 in 1 POUCH		
1		4 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	06/01/2023	

Labeler - ViolaCare, Inc. (119452160)

Establishment

Name	Address	ID/FEI	Business Operations
Dr Sabharwals Wound Care		862184668	manufacture(85231-100)

Revised: 5/2025

ViolaCare, Inc.