

THERACARE PAIN RELIEF MEDICATED- lidocaine and menthol patch

Veridian Healthcare

TheraCare 4% Lidocaine + Menthol

Active ingredients

Lidocaine 4%

Menthol 1%

Purposes

Topical anesthetic

Topical analgesic

Use

for the temporary relief minor pain

Warnings

For external use only

Do not use

- more than 1 patch on your body at a time
- on a 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 ask a doctor if

- 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 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 800-222-1222 right away.

Directions

adults and children 12 years of age and older:

- clean and dry affected area
- Carefully remove backing from patch starting at a corner
- Apply sticky side of patch to affected area
- use 1 patch for up to 12 hours
- Discard patch after single use

children under 12 years of age: consult a physician

Inactive ingredients

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

TheraCare Pain Relief Medicated



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lidocaine and menthol patch

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:71101-912
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
MENTHOL (UNII: L7T10EIP3A) (MENTHOL - UNII:L7T10EIP3A)	MENTHOL	1 g in 100 g

Inactive Ingredients

Ingredient Name	Strength
KAOLIN (UNII: 24H4NWX5CO)	
GLYCERIN (UNII: PDC6A3C0OX)	
METHYLPARABEN (UNII: A2I8C7HI9T)	

POLYACRYLIC ACID (250000 MW) (UNII: 9G2MAD7J6W)	
POLYSORBATE 80 (UNII: 6OZP39ZG8H)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
PROPYLPARABEN (UNII: Z8IX2SC1OH)	
SODIUM POLYACRYLATE (2500000 MW) (UNII: 05I15JNI2J)	
TARTARIC ACID (UNII: W4888I119H)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
DIHYDROXYALUMINUM AMINOACETATE ANHYDROUS (UNII: 1K713C615K)	
WATER (UNII: 059QF0KO0R)	
POVIDONE, UNSPECIFIED (UNII: FZ989GH94E)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:71101-912-05	5 g in 1 CARTON; Type 0: Not a Combination Product	12/01/2023	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M017	12/01/2023	

Labeler - Veridian Healthcare (830437997)

Establishment

Name	Address	ID/FEI	Business Operations
Foshan Aqua Gel Biotech Co., Ltd.,		529128763	manufacture(71101-912)