# HEALTHWISE LIDOCAINE AND MENTHOL PAIN RELIEF- lidocaine and menthol patch Veridian Healthcare

Disclaimer: Most OTC drugs are not reviewed and approved by FDA, however they may be marketed if they comply with applicable regulations and policies. FDA has not evaluated whether this product complies.

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#### HealthWise Lidocaine + Menthol Pain Relief Patch

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

#### PRINCIPAL DISPLAY PANEL



# **HEALTHWISE LIDOCAINE AND MENTHOL PAIN RELIEF**

lidocaine and menthol patch

Product Information				
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:71101-914	
Route of Administration	TOPICAL			

Active Ingredient/Active Moiety			
Ingredient Name	<b>Basis of Strength</b>	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
DIHYDROXYALUMINUM	1 AMINOACETATE ANHYDROUS (UNII: 1K713C615K)	
KAOLIN (UNII: 24H4NWX	5CO)	
GLYCERIN (UNII: PDC6A	3C0OX)	
METHYLPARABEN (UNII	I: A2I8C7HI9T)	
POLYACRYLIC ACID (2	<b>50000 MW)</b> (UNII: 9G2MAD7J6W)	
POLYSORBATE 80 (UNI	II: 60ZP39ZG8H)	

PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
PROPYLPARABEN (UNII: Z8IX2SC10H)	
SODIUM POLYACRYLATE (2500000 MW) (UNII: 05115JN12J)	
TARTARIC ACID (UNII: W4888I119H)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
WATER (UNII: 059QF0KO0R)	
POVIDONE, UNSPECIFIED (UNII: FZ989GH94E)	

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:71101-914- 05	5 g in 1 CARTON; Type 0: Not a Combination Product	10/01/2021	

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part348	10/01/2021	

# **Labeler -** Veridian Healthcare (830437997)

Establishment				
Name	Address	ID/FEI	<b>Business Operations</b>	
Foshan Aqua Gel Biotech Co., Ltd.,		529128763	manufacture(71101-914)	

Revised: 10/2021 Veridian Healthcare