MAXIMUM STRENGHT LIDOCAINE PLUS MENTHOL PAIN RELIEF PATCH-
lidocaine, menthol patch
Rite Aid Corporation

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.

Maximum Strenght Lidocaine plus Menthol Pain Relief Patch

Active Ingredients

Lidocaine 4.0% . . . . . Topical Anesthetic

Menthol 1.0% . . . . . Topical Anesthetic

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.

Dosage and Administration

Directions Adults and children 12 years of age and over :

■ Clean and dry affected area

■ Carefully remove backing from patch starting at a corner.

■ Apply sticky side of patch to affected area.

■ use one patch for up to 12 hours.

■ Discard patch after single use.

■Children under 12 years of age: consult a physician.

Other Safety Information

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

Inactive Ingredients

Carboxymethylcellulose sodium, Dihydroxyaluminum Aminoacetate, Glycerin, iodopropynyl butylcarbamate, Kaolin, petrolatum, Phenoxyethanol, polyacrylic acid, Polysorbate 80, Povidone, Propylene Glycol, Sodium Polyacrylate, Tartaric Acid, Titanium Dioxide, Water, 3-(2-ethylhexyloxy)propane-1,2-diol

Uses

Temporarily relieves minor pain.

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Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:11822-6514
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
LEVOMENTHOL (UNII: BZ1R15MTK7) (LEVOMENTHOL - UNII:BZ1R15MTK7)	LEVOMENTHOL	1 g in 100 g
LIDOCAINE (UNII: 98PI200987) (LIDOCAINE - UNII:98PI200987)	LIDOCAINE	4 g in 100 g

Inactive Ingredients

Ingredient Name	Strength
PETROLATUM (UNII: 4T6H12BN9U)	
CARBOXYMETHYLCELLULOSE SODIUM (UNII: K679OBS311)	
ETHYLHEXYLGLYCERIN (UNII: 147D247K3P)	
DIHYDROXYALUMINUM AMINOACETATE (UNII: DO250MG0W6)	
GLYCERIN (UNII: PDC6A3C0OX)	
KAOLIN (UNII: 24H4NWX5CO)	
POLYACRYLIC ACID (8000 MW) (UNII: 73861X4K5F)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
POLYSORBATE 80 (UNII: 6OZP39ZG8H)	
POLYETHYLENE GLYCOL 400 (UNII: B697894SGQ)	
POVIDONE, UNSPECIFIED (UNII: FZ989GH94E)	
SODIUM POLYACRYLATE (8000 MW) (UNII: 285CYO341L)	
TARTARIC ACID (UNII: W4888I119H)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
WATER (UNII: 059QF0KO0R)	
IODOPROPYNYL BUTYLCARBAMATE (UNII: 603P14DHEB)	

Product Characteristics

Color		**Score**	
Shape	RECTANGLE	**Size**	
Flavor		**Imprint Code**	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:11822-6514-1	5 in 1 CARTON	03/01/2021	
1		1 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 not final	part348	03/01/2021	

Labeler - Rite Aid Corporation (014578892)

Establishment

Name	Address	ID/FEI	Business Operations
Foshan Aqua Gel Biotech		529128763	manufacture(11822-6514)