RITE AID LIDOCAINE PATCH XLARGE- lidocaine 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.

Rite Aid Lidocaine Patch XLarge

Active Ingredients

Lidocaine 4%

Purpose

Topical anesthetic

Use

Temporary 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
- 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 or 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 as 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 1-800-222-1222 right away.

Directions

adults and children 12 years of age and over:

- clean and dry affected area
- carefully remove backing from patch starting at the 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 or age: consult a physician

Other Information

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

Inactive Ingredients

aluminum glycinate, carboxymethylcellulose sodium, 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



RITE AID LIDOCAINE PATCH XLARGE

lidocaine patch

Product Information

Product Type HUMAN OTC DRUG Item Code (Source) NDC:11822-9992

Route of Administration TOPICAL

Active Ingredient/Active Moiety

Ingredient NameBasis of StrengthStrengthLIDOCAINE (UNII: 98PI200987) (LIDOCAINE - UNII:98PI200987)LIDOCAINE 4 g in 100 g

Inactive Ingredients	
Ingredient Name	Strength
GLYCERIN (UNII: PDC6A3C0OX)	

POLYSORBATE 80 (UNII: 60ZP39ZG8H)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
POVIDONE (UNII: FZ 989GH94E)	
ETHYLHEXYLGLYCERIN (UNII: 147D247K3P)	
TARTARIC ACID (UNII: W48881119H)	
KAOLIN (UNII: 24H4NWX5CO)	
IODOPROPYNYL BUTYLCARBAMATE (UNII: 603P14DHEB)	
WATER (UNII: 059QF0KO0R)	
POLYACRYLIC ACID (8000 MW) (UNII: 73861X4K5F)	
CARBOXYMETHYLCELLULOSE SODIUM (UNII: K6790BS311)	
SODIUM POLYACRYLATE (8000 MW) (UNII: 285CYO341L)	
DIHYDROXYALUMINUM AMINOACETATE (UNII: DO250MG0W6)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
PETROLATUM (UNII: 4T6H12BN9U)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	

Packaging					
#	Item Code	Package Description	Marketing Start Date	Marketing End Date	
1	NDC:11822- 9992-3	3 in 1 CARTON	03/01/2023		
1		1 g in 1 POUCH; 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	03/01/2023			

Labeler - Rite Aid Corporation (014578892)

Establishment				
Name	Address	ID/FEI	Business Operations	
Foshan Aqua Gel Biotech Co., Ltd.		529128763	manufacture(11822-9992)	

Revised: 3/2023 Rite Aid Corporation