LIDOCAINE PAIN RELIEF GEL PATCH- lidocaine pain relief patch
Dynarex

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.

1454 Lidocaine Pain Relief Gel-Patch NDC 67777-009-40

Active Ingredients

Lidocaine 4%

Purpose

Topical anesthetic

Use

For temporary relief of pain

Warnings

For external use only

Do not use

- more than 1 patch at a time
- on wounds or damaged skin
- with a heating pad
- if you are allergic to any ingredients of this product

When using this product

- use only as directed
- avoid contact with the eyes, mucous membranes or rashes
- do not bandage tightly

Stop use and ask a doctor if

- localized skin reactions, such as rash, itching, redness, pain, swelling and blistering develop
- conditions worsen
- symptoms persist for more than 7 days
- symptoms clear up and occur again within a few days

if pregnant or breast feeding

ask a health professional before use

Keep out of reach of children.

If swallowed, get medical help or contact a Poison Control Center right away.

Directions

Adults and children 12 years of age and over:

- clean and dry affected area

- remove film from patch and apply to the skin
- apply 1 patch at a time to affected area, not more than 3 to 4 times daily
- patch should not be applied longer than an 8 hour period

Children under 12 years of age: consult a doctor

Other Information

- Avoid storing product in direct sunlight
- Protect product from excessive moisture

Inactive Ingredients

Dihydroxyaluminum Aminoacetate, Glycerol, Kaolin, Methylparaben, Polyacrylic Acid, Propylene Glycol, Propylparaben, PVP, Sodium Polyacrylate, Tartaric Acid, Titanium Dioxide, Tween 80, Water

Questions?

1-888-DYNAREX

Label

LIDOCAINE PAIN RELIEF GEL PATCH

lidocaine pain relief patch

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:67777-009
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
LIDOCAINE (UNII: 98PI200987) (LIDOCAINE - UNII:98PI200987)	LIDOCAINE	40 mg in 1000 mg

Inactive Ingredients	
Ingredient Name	**Strength**
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
POLYSORBATE 80 (UNII: 6OZP39ZG8H)	
METHYLPARABEN (UNII: A2I8C7HI9T)	
POVIDONE (UNII: FZ989GH94E)	
POLYACRYLIC ACID (8000 MW) (UNII: 73861X4K5F)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
PROPYLPARABEN (UNII: Z8IX2SC1OH)	
SODIUM POLYACRYLATE (8000 MW) (UNII: 285CYO341L)	
TARTARIC ACID (UNII: W4888I119H)	
WATER (UNII: 059QF0KO0R)	
GLYCERIN (UNII: PDC6A3C0OX)	
KAOLIN (UNII: 24H4NWX5CO)	
DIHYDROXYALUMINUM AMINOACETATE (UNII: DO250MG0W6)	

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:67777-009-40	60 in 1 CASE	08/27/2019	
1		5 in 1 BOX		
1		40 mg 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	08/27/2019	

Labeler - Dynarex (008124539)

Registrant - Dynarex (008124539)