PUREGEN LABS PAIN RELIEF 4 LIDOCAINE- lidocaine patch
Advanced Rx LLC

PUREGEN LABS Pain Relief 4% Lidocaine Patch

Drug Facts

Active ingredient

Lidocaine 4.00 %

Purpose

Topical Anesthetic

Uses:

- For the 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

- Avoid contact with the eyes

Stop use and ask a doctor if

- localized skin reactions occur, such as rash, itching, redness, irritation
- condition worsens, or if
- symptoms persist for more than 7 days or clear up and occur again within a few days.

Keep out of reach of children.

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

If pregnant or breast-feeding,

ask a health professional before use

Directions:

- Adults andchildren 12 years of age and older:
- Clean and dry the affected area
- Apply a patch at a time to the affected area; not more than 3 or 4 times daily to the affected area
- Remove the patch from the skin after at most 8 hours of application
- Children under 12 years of age: consult a doctor.

Other information:

- Store at 20-25°C (68-77°F) and protect from moisture.

Inactive ingredients

Aqua (Deionized Water), Dihydroxyaluminum Aminoacetate, Disodium EDTA, Glycerin, Methylparaben, Polyvinyl Alcohol, Propylene Glycol, Propylparaben, Sodium Carboxymethyl Cellulose, Sodium Polyacrylate, Tartaric Acid, Titanium Dioxide

Questions?

call toll-free 1-800-630-8895

Package Labeling:

PUREGEN LABS PAIN RELIEF 4 LIDOCAINE

lidocaine patch

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:80513-814
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
LIDOCAINE (UNII: 98PI200987) (LIDOCAINE - UNII:98PI200987)	LIDOCAINE	40 mg in 1 g

Inactive Ingredients	
Ingredient Name	**Strength**
WATER (UNII: 059QF0KO0R)	
DIHYDROXYALUMINUM AMINOACETATE (UNII: DO250MG0W6)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	
GLYCERIN (UNII: PDC6A3C0OX)	
METHYLPARABEN (UNII: A2I8C7HI9T)	

POLYVINYL ALCOHOL, UNSPECIFIED (UNII: 532B59J990)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
PROPYLPARABEN (UNII: Z8IX2SC1OH)	
CARBOXYMETHYLCELLULOSE SODIUM, UNSPECIFIED (UNII: K679OBS311)	
TARTARIC ACID (UNII: W4888I119H)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:80513-814-30	30 in 1 BOX	06/03/2024	
1		12 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 Drug	M017	06/03/2024	

Labeler - Advanced Rx LLC (042795108)

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