LIDOCAINE- lidocaine patch FORREAL PHARMACEUTICALS LLC

Disclaimer: This drug has not been found by FDA to be safe and effective, and this labeling has not been approved by FDA. For further information about unapproved drugs, click here.

Lidocaine 4%

Lidocaine 4%

Topical Anesthetic

For the temporary relief of pain

For external use only

Do not use

- More than 1 pathch 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 occur, such as rash, itching, redness, irritation, pain, swelling and blistering
- 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 the affected area
- Open pouch and remove one patch
- Apply 1 patch at a time to affected area; not more than 3 to 4 times daily
- Reseal pouch containing unused patches after each use
- Remove patch from the skin after at most 8-hour application

Children under 12 years of age: Consult a doctor

Other information:

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

Other ingredients: Acrylic Adhesive, Flaxseed oil, and Polysorbate 80

Questions or comments? 866-747-7365

Packaged For:

Forreal Pharmaceuticals LLC

Royal Oak, MI 48067

Questions or Comments please call 877-367-3250

NDC 81877-514-15

Qty:15 Patches

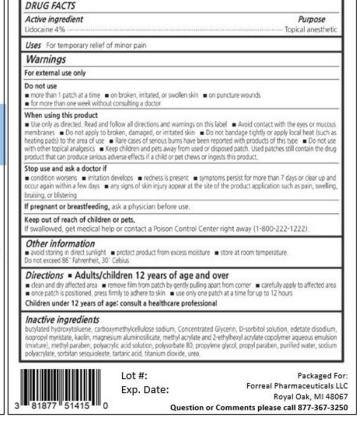
(5 per Resealable Pouch) x 3

Lidocaine 4%

Topical Pain Patch

for temporary pain relief





LIDOCAINE

lidocaine patch

Product Information

Product Type HUMAN OTC DRUG Item Code (Source) NDC:81877-514

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
BUTYLATED HYDROXYTOLUENE (UNII: 1P9D0Z171K)	
CARBOXYMETHYLCELLULOSE SODIUM (UNII: K6790BS311)	
GLYCERIN (UNII: PDC6A3C0OX)	
SORBITOL (UNII: 506T60A25R)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	
ISOPROPYL MYRISTATE (UNII: 0RE8K4LNJS)	
KAOLIN (UNII: 24H4NWX5CO)	
SILODRATE ANHYDROUS (UNII: 59110L5W24)	
2-ETHYLHEXYL ACRYLATE (UNII: HR49R9S6XG)	
METHYLPARABEN (UNII: A2I8C7HI9T)	
POLYACRYLIC ACID (250000 MW) (UNII: 9G2MAD7J6W)	
POLYSORBATE 80 (UNII: 6OZP39ZG8H)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
PROPYLPARABEN (UNII: Z8IX2SC1OH)	
WATER (UNII: 059QF0KO0R)	
SODIUM POLYACRYLATE (2500000 MW) (UNII: 05I15JNI2J)	
SORBITAN SESQUIOLEATE (UNII: 0W8RRI5W5A)	
TARTARIC ACID (UNII: W4888I119H)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
UREA (UNII: 8W8T17847W)	

Product Characteristics		
Color		Score
Shape	RECTANGLE (White Flexible Patch)	Size
Flavor		Imprint Code
Contains		

P	Packaging			
#	ltem Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:81877- 514-15	3 in 1 BOX	06/27/2022	
1		1 g in 1 POUCH; Type 2: Prefilled Drug Delivery Device/System (syringe, patch, etc.)		

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
unapproved drug other		06/27/2022	

Labeler - FORREAL PHARMACEUTICALS LLC (118029197)

Revised: 1/2023 FORREAL PHARMACEUTICALS LLC