

**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.*

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**Lidocaine 4%**

Lidocaine 4%

Topical Anesthetic

For the temporary relief of pain

**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 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**

<p>NDC: 81877-514-15</p>  <p><b>Forreal Pharmaceuticals LLC</b> YOUR SOLUTION TO BETTER HEALTHCARE</p> <p>Qty:15 Patches (5 per Resealable Pouch) x 3</p>	<p><b>Lidocaine 4%</b></p> <p><b>Topical Pain Patch</b> <i>for temporary pain relief</i></p>	<p><b>DRUG FACTS</b></p> <table border="1"> <thead> <tr> <th>Active ingredient</th> <th>Purpose</th> </tr> </thead> <tbody> <tr> <td>Lidocaine 4%</td> <td>Topical anesthetic</td> </tr> </tbody> </table> <p><b>Uses</b> For temporary relief of minor pain</p> <p><b>Warnings</b></p> <p><b>For external use only</b></p> <p><b>Do not use</b></p> <ul style="list-style-type: none"> <li>■ more than 1 patch at a time</li> <li>■ on broken, irritated, or swollen skin</li> <li>■ on puncture wounds</li> <li>■ for more than one week without consulting a doctor</li> </ul> <p><b>When using this product</b></p> <ul style="list-style-type: none"> <li>■ Use only as directed. Read and follow all directions and warnings on this label</li> <li>■ Avoid contact with the eyes or mucous membranes</li> <li>■ Do not apply to broken, damaged, or irritated skin</li> <li>■ Do not bandage tightly or apply local heat (such as heating pads) to the area of use</li> <li>■ Rare cases of serious burns have been reported with products of this type</li> <li>■ Do not use with other topical analgesics</li> <li>■ Keep children and pets away from used or disposed patch. Used patches still contain the drug product that can produce serious adverse effects if a child or pet chews or ingests this product.</li> </ul> <p><b>Stop use and ask a doctor if</b></p> <ul style="list-style-type: none"> <li>■ condition worsens</li> <li>■ irritation develops</li> <li>■ redness is present</li> <li>■ symptoms persist for more than 7 days or clear up and occur again within a few days</li> <li>■ any signs of skin injury appear at the site of the product application such as pain, swelling, bruising, or blistering</li> </ul> <p><b>If pregnant or breastfeeding, ask a physician before use.</b></p> <p><b>Keep out of reach of children or pets.</b> If swallowed, get medical help or contact a Poison Control Center right away (1-800-222-1222).</p> <p><b>Other information</b></p> <ul style="list-style-type: none"> <li>■ avoid storing in direct sunlight</li> <li>■ protect product from excess moisture</li> <li>■ store at room temperature. Do not exceed 86° Fahrenheit, 30° Celsius</li> </ul> <p><b>Directions</b> ■ <b>Adults/children 12 years of age and over</b></p> <ul style="list-style-type: none"> <li>■ clean and dry affected area</li> <li>■ remove film from patch by gently pulling apart from corner</li> <li>■ carefully apply to affected area</li> <li>■ once patch is positioned, press firmly to adhere to skin</li> <li>■ use only one patch at a time for up to 12 hours</li> </ul> <p><b>Children under 12 years of age: consult a healthcare professional</b></p> <p><b>Inactive ingredients</b> butylated hydroxytoluene, carboxymethylcellulose sodium, Concentrated Glycerin, D-sorbitol solution, edetate disodium, isopropyl myristate, kaolin, magnesium aluminosilicate, methyl acrylate and 2-ethylhexyl acrylate copolymer aqueous emulsion (mixture), methyl paraben, polyacrylic acid solution, polysorbate 80, propylene glycol, propyl paraben, purified water, sodium polyacrylate, sorbitan sesquioleate, tartaric acid, titanium dioxide, urea.</p>	Active ingredient	Purpose	Lidocaine 4%	Topical anesthetic
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Lidocaine 4%	Topical anesthetic					
		 <p>3 81877 51415 0</p> <p>Lot #: _____ Exp. Date: _____</p> <p>Packaged For: Forreal Pharmaceuticals LLC Royal Oak, MI 48067</p> <p><b>Question or Comments please call 877-367-3250</b></p>				

**LIDOCAINE**

lidocaine patch

**Product Information**

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:81877-514
<b>Route of Administration</b>	TOPICAL		

**Active Ingredient/Active Moiety**

<b>Ingredient Name</b>	<b>Basis of Strength</b>	<b>Strength</b>
LIDOCAINE (UNII: 98PI200987) (LIDOCAINE - UNII:98PI200987)	LIDOCAINE	40 mg in 1 g

**Inactive Ingredients**

<b>Ingredient Name</b>	<b>Strength</b>
BUTYLATED HYDROXYTOLUENE (UNII: 1P9D0Z171K)	
CARBOXYMETHYLCELLULOSE SODIUM (UNII: K679OBS311)	
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: 05I15JN12J)	
SORBITAN SESQUIOLEATE (UNII: 0W8RRI5W5A)	
TARTARIC ACID (UNII: W4888I119H)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
UREA (UNII: 8W8T17847W)	

**Product Characteristics**

<b>Color</b>		<b>Score</b>	
<b>Shape</b>	RECTANGLE (White Flexible Patch)	<b>Size</b>	
<b>Flavor</b>		<b>Imprint Code</b>	
<b>Contains</b>			

**Packaging**

<b>#</b>	<b>Item Code</b>	<b>Package Description</b>	<b>Marketing Start Date</b>	<b>Marketing End Date</b>
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