

## **ORVEX- lidocaine and menthol Florrx Pharmaceutical**

*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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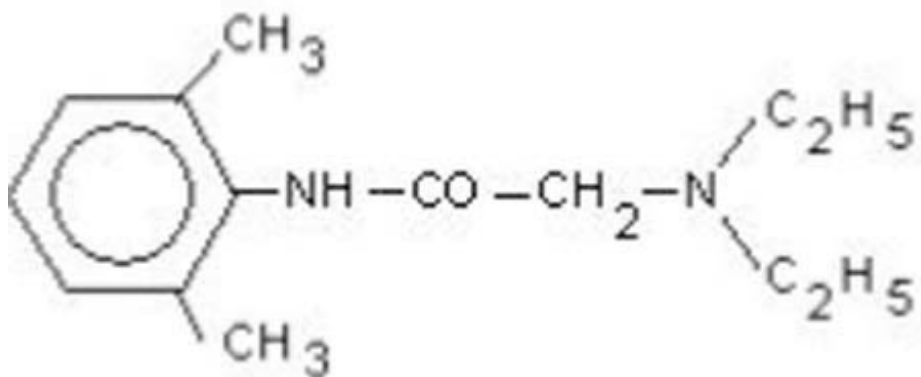
### **Lidocaine Patch and Menthol**

#### **Lidocaine Patch 5% & Menthol Roll-on Gel Rx Only**

#### **DESCRIPTION**

Lidocaine patch 5% is comprised of an adhesive material containing 5% lidocaine, USP, which is applied to a non-woven polyester backing and covered with a polyethylene terephthalate (PET) film release liner. The release liner is removed prior to application to the skin. The size of the patch is 10 cm × 14 cm.

Lidocaine, USP is chemically designated as acetamide, 2-(diethylamino)-N-(2,6-dimethylphenyl), has an octanol: water partition ratio of 43 at pH 7.4, and has the following structure:



Each adhesive patch contains 700 mg of lidocaine, USP (50 mg per gram adhesive) in an aqueous base. It also contains the following inactive ingredients: dihydroxyaluminum aminoacetate, disodium edetate, gelatin, glycerin, kaolin, methylparaben, polyvinyl alcohol, propylparaben, propylene glycol, sodium carboxymethylcellulose, partially neutralized sodium polyacrylate, D-sorbitol, tartaric acid, and urea.

#### **CLINICAL STUDIES**

Single-dose treatment with lidocaine patch 5% was compared to treatment with vehicle patch (without lidocaine), and to no treatment (observation only) in a double-blind, crossover clinical trial with 35 post-herpetic neuralgia patients. Pain intensity and pain

relief scores were evaluated periodically for 12 hours. Lidocaine patch 5% performed statistically better than vehicle patch in terms of pain intensity from 4 to 12 hours.

Multiple-dose, two-week treatment with lidocaine patch 5% was compared to vehicle patch (without lidocaine) in a double-blind, crossover clinical trial of withdrawal-type design conducted in 32 patients, who were considered as responders to the open-label use of lidocaine patch 5% prior to the study. The constant type of pain was evaluated but not the pain induced by sensory stimuli (dysesthesia). Statistically significant differences favoring lidocaine patch 5% were observed in terms of time to exit from the trial (14 versus 3.8 days at  $p$ -value  $<0.001$ ), daily average pain relief, and patient's preference of treatment. About half of the patients also took oral medication commonly used in the treatment of post-herpetic neuralgia. The extent of use of concomitant medication was similar in the two treatment groups.

## **INDICATION AND USAGE**

Lidocaine patch 5% is indicated for relief of pain associated with post-herpetic neuralgia. It should be applied only to **intact skin**.

## **CONTRAINDICATIONS**

Lidocaine patch 5% is contraindicated in patients with a known history of sensitivity to local anesthetics of the amide type, or to any other component of the product.

## **WARNINGS**

### **Risk of Methemoglobinemia**

Cases of methemoglobinemia have been reported in association with local anesthetic use. Although all patients are at risk for methemoglobinemia, patients with glucose-6-phosphate dehydrogenase deficiency, congenital or idiopathic methemoglobinemia, cardiac or pulmonary compromise, infants under 6 months of age, and concurrent exposure to oxidizing agents or their metabolites are more susceptible to developing clinical manifestations of the condition. If local anesthetics must be used in these patients, close monitoring for symptoms and signs of methemoglobinemia is recommended.

Signs of methemoglobinemia may occur immediately or may be delayed some hours after exposure, and are characterized by a cyanotic skin discoloration and/or abnormal coloration of the blood. Methemoglobin levels may continue to rise; therefore, immediate treatment is required to avert more serious central nervous system and cardiovascular adverse effects, including seizures, coma, arrhythmias, and death. Discontinue lidocaine and any other oxidizing agents. Depending on the severity of the signs and symptoms, patients may respond to supportive care, i.e. oxygen therapy, hydration. A more severe clinical presentation may require treatment with methylene blue, exchange transfusion, or hyperbaric oxygen.

### **Accidental Exposure in Children**

Even a *used* lidocaine patch contains a large amount of lidocaine (at least 665 mg). The potential exists for a small child or a pet to suffer serious adverse effects from chewing

or ingesting a new or used lidocaine patch, although the risk with this formulation has not been evaluated. It is important for patients to **store and dispose of lidocaine patch 5% out of the reach of children, pets and others** (see **HANDLING AND DISPOSAL**).

### **Excessive Dosing**

Excessive dosing by applying lidocaine patch 5% to larger areas or for longer than the recommended wearing time could result in increased absorption of lidocaine and high blood concentrations, leading to serious adverse effects (see **ADVERSE REACTIONS, Systemic Reactions**). Lidocaine toxicity could be expected at lidocaine blood concentrations above 5 mcg/mL. The blood concentration of lidocaine is determined by the rate of systemic absorption and elimination. Longer duration of application, application of more than the recommended number of patches, smaller patients, or impaired elimination may all contribute to increasing the blood concentration of lidocaine. With recommended dosing of lidocaine patch 5%, the average peak blood concentration is about 0.13 mcg/mL, but concentrations higher than 0.25 mcg/mL have been observed in some individuals.

## **ADVERSE REACTIONS**

**Application Site Reactions** During or immediately after treatment with lidocaine patch 5%, the skin at the site of application may develop blisters, bruising, burning sensation, depigmentation, dermatitis, discoloration, edema, erythema, exfoliation, irritation, papules, petechia, pruritus, vesicles, or may be the locus of abnormal sensation. These reactions are generally mild and transient, resolving spontaneously within a few minutes to hours.

**Allergic Reactions** Allergic and anaphylactoid reactions associated with lidocaine, although rare, can occur. They are characterized by angioedema, bronchospasm, dermatitis, dyspnea, hypersensitivity, laryngospasm, pruritus, shock, and urticaria. If they occur, they should be managed by conventional means. The detection of sensitivity by skin testing is of doubtful value.

**Other Adverse Events** Due to the nature and limitation of spontaneous reports in postmarketing surveillance, causality has not been established for additional reported adverse events including:

Asthenia, confusion, disorientation, dizziness, headache, hyperesthesia, hypoesthesia, lightheadedness, metallic taste, nausea, nervousness, pain exacerbated, paresthesia, somnolence, taste alteration, vomiting, visual disturbances such as blurred vision, flushing, tinnitus, and tremor.

**Systemic (Dose-Related) Reactions** Systemic adverse reactions following appropriate use of lidocaine patch 5% are unlikely, due to the small dose absorbed (see **CLINICAL PHARMACOLOGY, Pharmacokinetics**). Systemic adverse effects of lidocaine are similar in nature to those observed with other amide local anesthetic agents, including CNS excitation and/or depression (light-headedness, nervousness, apprehension, euphoria, confusion, dizziness, drowsiness, tinnitus, blurred or double vision, vomiting, sensations of heat, cold or numbness, twitching, tremors, convulsions, unconsciousness, respiratory depression and arrest). Excitatory CNS reactions may be brief or not occur at all, in which case the first manifestation may be drowsiness

merging into unconsciousness. Cardiovascular manifestations may include bradycardia, hypotension and cardiovascular collapse leading to arrest.

## **OVERDOSAGE**

Lidocaine overdose from cutaneous absorption is rare, but could occur. If there is any suspicion of lidocaine overdose (see **ADVERSE REACTIONS, Systemic Reactions**), drug blood concentration should be checked. The management of overdose includes close monitoring, supportive care, and symptomatic treatment. Dialysis is of negligible value in the treatment of acute overdose with lidocaine.

In the absence of massive topical overdose or oral ingestion, evaluation of symptoms of toxicity should include consideration of other etiologies for the clinical effects, or overdosage from other sources of lidocaine or other local anesthetics.

The oral LD<sub>50</sub> of lidocaine HCl is 459 (346 to 773) mg/kg (as the salt) in non-fasted female rats and 214 (159 to 324) mg/kg (as the salt) in fasted female rats, which are equivalent to roughly 4000 mg and 2000 mg, respectively, in a 60 kg to 70 kg man based on the equivalent surface area dosage conversion factors between species.

## **DOSAGE AND ADMINISTRATION**

Apply lidocaine patch 5% to intact skin to cover the most painful area. Apply the prescribed number of patches (maximum of 3), only once for up to 12 hours within a 24 hour period. Patches may be cut into smaller sizes with scissors prior to removal of the release liner (see **HANDLING AND DISPOSAL**). Clothing may be worn over the area of application. Smaller areas of treatment are recommended in a debilitated patient, or a patient with impaired elimination.

If irritation or a burning sensation occurs during application, remove the patch(es) and do not reapply until the irritation subsides.

When lidocaine patch 5% is used concomitantly with other products containing local anesthetic agents, the amount absorbed from all formulations must be considered.

Lidocaine patch 5% may not stick if it gets wet. Avoid contact with water, such as bathing, swimming or showering.

## **HANDLING AND DISPOSAL**

Hands should be washed after the handling of lidocaine patch 5%, and eye contact with lidocaine patch 5% should be avoided. Do not store patch outside the sealed envelope. Apply immediately after removal from the protective envelope. Fold used patches so that the adhesive side sticks to itself and safely discard used patches or pieces of cut patches where children and pets cannot get to them. Lidocaine patch 5% should be kept out of the reach of children.

## **HOW SUPPLIED**

Lidocaine patch 5% is available as the following:

Carton of 30 patches, packaged into individual child-resistant envelopes.

NDC 65162-791-08

Store at 20° to 25°C (68° to 77°F); excursions permitted between 15° to 30°C (59° to 86°F) [see USP Controlled Room Temperature].

For more information, call Amneal Pharmaceuticals at 1-877-835-5472.

Distributed by:

**Amneal Pharmaceuticals LLC**

Bridgewater, NJ 08807

Rev. 10-2020-03

**PRINCIPAL DISPLAY PANEL**



Cut along the dotted line

NDC 65162-**791**-04

## Lidocaine Patch 5%

Each adhesive patch contains:

Lidocaine ..... 700 mg (50 mg per gram  
adhesive) in an aqueous base.

Methylparaben and propylparaben as preservatives.

**Usual Dosage:** Apply up to 3 patches. See package insert for complete prescribing information.

Store at 20° to 25°C (68° to 77°F); excursions permitted to 15° to 30°C (59° to 86°F) [See USP Controlled Room Temperature].

**WARNING:** Keep used and unused patches out of the reach of children, pets and others.

Manufactured by:

**Amneal Pharmaceuticals**

Piscataway, NJ 08854

Distributed by:

**Amneal Pharmaceuticals**

Glasgow, KY 42141

Rev. 07-2015-00

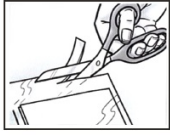
**Rx only**

**1 Patch**  
(10 cm x 14 cm)



## Directions for Use

Do not store patch outside the sealed envelope.



Cut the envelope along the dotted line. Patches may be cut into smaller sizes with scissors prior to removal of the release liner. Safely discard the remaining unused pieces of cut patches where children and pets cannot get to them.



Remove the transparent release liner (clear plastic backing) before application of patch to the skin. Apply immediately after removal from the protective envelope.



Apply the prescribed number of patches, only once for up to 12 hours within a 24 hour period. Remove patches if irritation occurs.

Placement of external heat sources, such as heating pads or electric blankets, over Lidocaine Patch 5% is not recommended.

Lidocaine Patch 5% may not stick if it gets wet. Avoid contact with water, such as bathing, swimming or showering.

Fold used patches so that the adhesive side sticks to itself and safely discard used patches or pieces of cut patches where children and pets cannot get to them.



N  
3 65162 79104 4

LOT:  
EXP:

NDC 65162-791-08

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**WARNING:** Keep used and unused patches out of the reach of children, pets and others.

**Rx only**

**30 PATCHES**  
30 Envelopes  
Containing 1 Patch Each



# Lidocaine Patch 5%

Manufactured by:  
**Amneal Pharmaceuticals**  
Piscataway, NJ 08854

Distributed by:  
**Amneal Pharmaceuticals**  
Glasgow, KY 42141

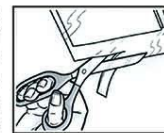
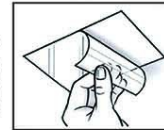
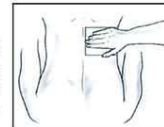
Rev. 07-2019-02



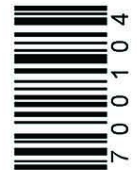
Placement of external heat sources, such as heating pads or electric blankets, over Lidocaine Patch 5% is not recommended. Lidocaine Patch 5% may not stick if it gets wet. Avoid contact with water, such as bathing, swimming or showering. Fold used patches so that the adhesive side sticks to itself and safely discard used patches or pieces of cut patches where children and pets cannot get to them.

Cut the envelope along the dotted line. Patches may be cut into smaller sizes with scissors prior to removal of the release liner. Safely discard the remaining unused pieces of cut patches where children and pets cannot get to them. Remove the transparent release liner (clear plastic backing) before application of patches to the skin. Apply immediately after removal from the protective envelope.

Apply the prescribed number of patches, only once for up to 12 hours within a 24 hour period. Remove patches if irritation occurs.



**Directions for Use**  
Do not store patch outside the sealed envelope.



70mm x 30 mm  
Non-Varnish Area for  
Lot # & Exp Date  
and Serialization

NDC 65162-791-08

# Lidocaine Patch 5%





HealthWise Roll-on Menthol Pain Relief Gel

HealthWise Rol-on Menthol Pain Relief Gel

Active Ingredient

Menthol 6%

When using this product avoid contacts with the eyes or mucous membranes. do not apply to wounds or damaged skin. do not apply to irritated skin. do not bandage. wash hands after use with cool water. do not use with heating pad or device.

Menthol 6%-----Topical Analgesic

For external use only.

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

keep out of reach of children if swallowed, get medical help or contact a poison Control Center Immediately.

Inactive ingredients alcohol, aloe barbadensis leaf juice, aminomethyl propanol, arctium lappa extract, arnica montana flower extract, camelia sinensis leaf extract, camphor, carbomer, chamomila recutita (matricaria) flower water, glycerin, ilex paraguariensis leaf extract, isopropyl myristate, maltodextrin, water

Direction: Apply to affected area not more than 3 to 4 times daily.

**Drug Facts**

Active ingredient	Purpose
Menthol 6%	Topical analgesic

**Uses:** Temporarily relieves minor pain associated with: ■ arthritis ■ simple backache ■ muscle strains ■ sprains ■ bruises

**Warnings:** For external use only.

**When using this product:** ■ use only as directed. Read and follow all directions and warnings on this carton ■ rare cases of serious burns have been reported with products of this type ■ do not bandage tightly or apply local heat (such as heating pads) or a medicated patch to the area of use ■ avoid contact with eyes and mucous membranes ■ do not apply to wounds or damaged, broken or irritated skin ■ a transient burning sensation may occur upon application but generally disappears in several days ■ if severe burning sensation occurs, discontinue use immediately ■ do not expose the area treated with product to heat or direct sunlight ■ avoid applying into skin folds

**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

**Flammable:** ■ keep away from fire or flame

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 Poison Control Center (1-800-222-1222) right away.

**Directions**

**Adults and children 2 years of age and older:** ■ Apply to affected area no more than 3 to 4 times daily.

**Children under 2 years of age:** ■ Do not use, ask a doctor.

**Other information:** ■ Store at 20°C-25°C (68°F-77°F) ■ Store in cool dry place away from direct sunlight

**Inactive ingredients:** alcohol, aloe barbadensis leaf juice, aminomethyl propanol, arctium lappa extract, amica montana flower extract, camilla sinensis leaf extract, camphor, carbomer, chamomilla recutita (matricaria) flower water, glycerin, hex paraguayensis leaf extract, isopropyl myristate, maltodextrin, water

Questions or comments? Call 1-888-326-1313

**DO NOT USE IF TAMPER SEAL IS BROKEN OR MISSING.  
CLOSE CAP TIGHTLY BETWEEN USES.  
KEEP THIS OUTER CARTON AS IT CONTAINS IMPORTANT INFORMATION.**

HealthWise®  
Manufactured for:  
Veridian Healthcare, LLC  
1175 Lakeside Drive  
Gurnee, IL 60031 USA  
www.VeridianHealthcare.com  
Made in China



92.99100 05/25 VC510047  
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pdp



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### PRINCIPAL DISPLAY PANEL

The packaging for Orvex is shown below.



## Product Information

<b>Product Type</b>	HUMAN PRESCRIPTION DRUG	<b>Item Code (Source)</b>	NDC:84460-802
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## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:84460-802-01	1 in 1 KIT; Type 0: Not a Combination Product	03/24/2026	

## Quantity of Parts

Part #	Package Quantity	Total Product Quantity
Part 1	30 POUCH	30
Part 2	1 BOTTLE, PLASTIC	89 g

## Part 1 of 2

### LIDOCAINE

lidocaine patch

## Product Information

<b>Item Code (Source)</b>	NDC:65162-791
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<b>Route of Administration</b>	TOPICAL
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## Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
LIDOCAINE (UNII: 98PI200987) (LIDOCAINE - UNII:98PI200987)	LIDOCAINE	700 mg

## Inactive Ingredients

Ingredient Name	Strength
DIHYDROXYALUMINUM AMINOACETATE (UNII: DO250MG0W6)	
EDETATE SODIUM (UNII: MP1J8420LU)	
GELATIN (UNII: 2G86QN327L)	
GLYCERIN (UNII: PDC6A3C0OX)	
KAOLIN (UNII: 24H4NWX5CO)	
METHYLPARABEN (UNII: A2I8C7HI9T)	
POLYVINYL ALCOHOL, UNSPECIFIED (UNII: 532B59J990)	
PROPYLPARABEN (UNII: Z8IX2SC1OH)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
CARBOXYMETHYLCELLULOSE SODIUM (UNII: K679OBS311)	
SODIUM POLYACRYLATE (8000 MW) (UNII: 285CYO341L)	

**SORBITOL** (UNII: 506T60A25R)

**TARTARIC ACID** (UNII: W4888I119H)

**UREA** (UNII: 8W8T17847W)

## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:65162-791-08	30 in 1 CARTON		
1		1 in 1 POUCH; Type 0: Not a Combination Product		

## Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA206463	08/25/2020	

## Part 2 of 2

### MYDERM PRO FREEZE COOLING MENTHOL PAIN RELIEF ROLL-ON

menthol gel

## Product Information

**Item Code (Source)** NDC:72667-073

**Route of Administration** TOPICAL

## Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
<b>menthol</b> (UNII: L7T10EIP3A) (MENTHOL - UNII:L7T10EIP3A)	menthol	6 g in 100 g

## Inactive Ingredients

Ingredient Name	Strength
<b>ALCOHOL</b> (UNII: 3K9958V90M)	
<b>ALOE BARBADENSIS LEAF JUICE</b> (UNII: RUE8E6T4NB)	
<b>AMINOMETHYL PROPANOL</b> (UNII: LU49E6626Q)	
<b>ARCTIUM LAPPA FRUIT OIL</b> (UNII: 5Q5BO6MFW2)	
<b>ARNICA MONTANA FLOWER WATER</b> (UNII: U7L2JP51PR)	
<b>CAMELLIA SINENSIS LEAF OIL</b> (UNII: VC855RRT77)	
<b>CAMPHOR (SYNTHETIC)</b> (UNII: 5TJD82A1ET)	
<b>CARBOMER</b> (UNII: 0A5MM307FC)	
<b>CHAMOMILE FLOWER OIL</b> (UNII: 60F80Z61A9)	
<b>GLYCERIN</b> (UNII: PDC6A3C0OX)	

<b>ILEX PARAGUARIENSIS LEAF</b> (UNII: 1Q953B4O4F)	
<b>ISOPROPYL MYRISTATE</b> (UNII: 0RE8K4LNJS)	
<b>MALTODEXTRIN</b> (UNII: 7CVR7L4A2D)	
<b>WATER</b> (UNII: 059QF0KO0R)	

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:72667-073-01	89 g in 1 BOTTLE, PLASTIC; 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	03/06/2024	

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
unapproved drug other		07/01/2025	

**Labeler** - Florrax Pharmaceutical (119257612)

### Establishment

Name	Address	ID/FEI	Business Operations
Amneal Pharmaceuticals, LLC		053542455	analysis(65162-791) , label(65162-791) , manufacture(65162-791) , pack(65162-791)

### Establishment

Name	Address	ID/FEI	Business Operations
Florrax Pharmaceutical Corp.		119257612	label(84460-802)

Revised: 3/2026

Florrax Pharmaceutical