

**THERAWORX PAIN RELIEF ROLL- ON- LIDOCAINE- lidocaine  
hydrochloride liquid  
AVADIM HOLDINGS, INC.**

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**Theraworx Pain Relief Roll- On- Lidocaine**

***Drug Facts***

***Active Ingredient***

Lidocaine Hydrochloride 4.00%

***Purpose***

Topical analgesic

***Uses***

For temporary relief of pain

***Warnings***

**For external use only.**

**Do not use**

in large quantities, particularly over raw surfaces or blistered areas

**When using this product**

avoid contact with the eyes

**Stop use and ask a doctor if**

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

***Directions***

- Adults and children 2 years of age and older:
- shake bottle well
- roll a thin layer to each affected area and allow to air dry
- repeat
- Wash hands after applying product
- do not use more than 3 to 4 times daily

- children under 2 years of age do not use: consult a doctor

### Other Information

Store between 32°F and 120°F

### Inactive Ingredients (Alphabetical)

Allantoin, Aloe barbadensis Leaf Extract, Aqua (Water), Benzyl Alcohol, Citric Acid, Cocamidopropyl Betaine, Decyl Glucoside, Dimethyl Sulfoxide, Ethylhexylglycerin, Glycerin, Potassium Sorbate, Sanguinaria canadensis Root Extract, Silver Hydrosol, Sodium Benzoate, Tetrasodium EDTA, Xanthan Gum, Yeast Extract, Zingiber (Ginger) Root Extract

### Package Labeling:

**Drug Facts (continued)**

**Other Information**  
Store between 32°F and 120°F

**Inactive Ingredients (Alphabetical)**  
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**This package is child-resistant. Replace cap tightly**

(NDC)  
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**Theraworx®**

CLINICALLY TRUSTED

MAXIMUM STRENGTH  
**PAIN RELIEF**  
**ROLL-ON**  
LIDOCAINE HCL 4%

Fast-acting  
Targets nerves  
2.5 fl oz (74 mL)

**MADE WITH GINGER**

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**Active Ingredient**  
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**Uses** For temporary relief of pain

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**Keep out of reach of children** If swallowed, get medical help or contact a Poison Control Center right away

**Directions**  
■ Adults and children 2 years of age and older: ■ shake bottle well ■ roll a thin layer to each affected area and allow to air dry ■ repeat ■ Wash hands after applying product ■ do not use more than 3 to 4 times daily ■ children under 2 years of age do not use: consult a doctor

Theraworx® is a trademark of and manufactured by Avadim Health Swannanoa, NC 28778 1-877-677-2723 NRV-25R • MA-9-007 • 2.5 fl oz (74 mL) [theraworx.com](http://theraworx.com)

## THERAWORX PAIN RELIEF ROLL- ON- LIDOCAINE

lidocaine hydrochloride liquid

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:61594-028
<b>Route of Administration</b>	TOPICAL		

## Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
<b>LIDOCAINE HYDROCHLORIDE</b> (UNII: V13007Z41A) (LIDOCAINE - UNII:98PI200987)	LIDOCAINE	40 mg in 1 mL

## Inactive Ingredients

Ingredient Name	Strength
<b>ALLANTOIN</b> (UNII: 344S277G0Z)	
<b>ALOE VERA LEAF</b> (UNII: ZY81Z83H0X)	
<b>WATER</b> (UNII: 059QF0KO0R)	
<b>BENZYL ALCOHOL</b> (UNII: LKG8494WBH)	
<b>CITRIC ACID MONOHYDRATE</b> (UNII: 2968PHW8QP)	
<b>COCAMIDOPROPYL BETAINE</b> (UNII: 5OCF3O11KX)	
<b>DECYL GLUCOSIDE</b> (UNII: Z17H97EA6Y)	
<b>DIMETHYL SULFOXIDE</b> (UNII: YOW8V9698H)	
<b>ETHYLHEXYLGLYCERIN</b> (UNII: 147D247K3P)	
<b>GLYCERIN</b> (UNII: PDC6A3C0OX)	
<b>POTASSIUM SORBATE</b> (UNII: 1VPU26JZZ4)	
<b>SANGUINARIA CANADENSIS ROOT</b> (UNII: N9288CD508)	
<b>SODIUM BENZOATE</b> (UNII: OJ245FE5EU)	
<b>EDETATE SODIUM</b> (UNII: MP1J8420LU)	
<b>XANTHAN GUM</b> (UNII: TTV12P4NEE)	
<b>YEAST, UNSPECIFIED</b> (UNII: 3NY3SM6B8U)	
<b>GINGER</b> (UNII: C5529G5JPQ)	

## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:61594-028-00	1 in 1 CARTON	01/15/2024	
1		74 mL in 1 BOTTLE; 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	01/15/2024	

**Labeler** - AVADIM HOLDINGS, INC. (118512488)