

**THERAWORX PM NIGHTTIME MAXIMUM STRENGTH PAIN RELIEF- lidocaine hydrochloride liquid**  
**AVADIM HOLDINGS, INC.**

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**Theraworx PM Nighttime Maximum Strength Pain Relief Roll-On**

***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 bilstered 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.

**If pregnant or breastfeeding,**

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 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, Parfum (Fragrance), Potassium Sorbate, Sanguinaria canadensis Root Extract, Silver Hydrosol, Sodium Benzoate, Tetrasodium EDTA, Xanthan Gum, Yeast Extract, Zingiber (Ginger) Root Extract

**☐ This package is child -resistant. Replace cap tightly**

### Package Labeling:

<p><b>Drug Facts</b> (continued)</p> <p><b>Directions</b></p> <p>■ 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</p>	<p style="text-align: center;">CLINICALLY TRUSTED</p>  <p style="text-align: center;"><b>Theraworx</b><sup>®</sup></p> <p style="text-align: center;">PM</p>  <p style="text-align: center;"><b>NIGHTTIME</b></p> <p style="text-align: center;">MAXIMUM STRENGTH</p> <p style="text-align: center;"><b>PAIN RELIEF</b></p> <p style="text-align: center;"><b>ROLL-ON</b></p> <p style="text-align: center;">LIDOCAINE HCL 4 %</p> <p style="text-align: center;">Lasting Relief • Lavender Vanilla Scent</p> <p style="text-align: center;">2.5 fl oz (74 mL)</p>	<p><b>Drug Facts</b></p> <p><b>Active Ingredient</b> Lidocaine Hydrochloride 4.00%</p> <p><b>Purpose</b> Topical analgesic</p> <p><b>Uses</b> For temporary relief of pain</p> <p><b>Warnings</b> <b>For external use only.</b></p> <p><b>Do not use</b> in large quantities, particularly over raw surfaces or blistered areas.</p> <p><b>When using this product</b> avoid contact with the eyes.</p> <p><b>Stop use and ask a doctor if</b> condition worsens, or if symptoms persist for more than 7 days or clear up and occur again within a few days.</p> <p><b>If pregnant or breastfeeding,</b> ask a health professional before use.</p> <p><b>Keep out of reach of children.</b> If swallowed, get medical help or contact a Poison Control Center right away.</p>
<p><b>Other Information</b> Store between 32°F and 120°F</p> <p><b>Inactive Ingredients</b> (Alphabetical) Allantoin, Aloe barbadensis Leaf Extract, Aqua (Water), Benzyl Alcohol, Citric Acid, Cocamidopropyl Betaine, Decyl Glucoside, Dimethyl Sulfoxide, Ethylhexylglycerin, Glycerin, Parfum (Fragrance), Potassium Sorbate, Sanguinaria canadensis Root Extract, Silver Hydrosol, Sodium Benzoate, Tetrasodium EDTA, Xanthan Gum, Yeast Extract, Zingiber (Ginger) Root Extract</p> <p><b>This package is child-resistant. Replace cap tightly</b></p>		<p style="text-align: right;">NDC 00000-000-00</p>  <p>Theraworx® is a trademark of and manufactured for Avadim Health Swannanoa, NC 28778 1-877-677-2723 NTR-25R • MA-6-191 • 2.5 fl oz (74 mL) <a href="http://theraworx.com">theraworx.com</a></p>

Store between 32°F and 120°F



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# THERAWORX PM NIGHTTIME MAXIMUM STRENGTH PAIN RELIEF

lidocaine hydrochloride liquid

## Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:61594-044
<b>Route of Administration</b>	TOPICAL		

## Active Ingredient/Active Moiety

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

## Inactive Ingredients

<b>Ingredient Name</b>	<b>Strength</b>
<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

<b>#</b>	<b>Item Code</b>	<b>Package Description</b>	<b>Marketing Start Date</b>	<b>Marketing End Date</b>
1	NDC:61594-044-00	1 in 1 CARTON	09/01/2024	
1		74 mL in 1 BOTTLE; Type 0: Not a Combination Product		

## Marketing Information

<b>Marketing Category</b>	<b>Application Number or Monograph Citation</b>	<b>Marketing Start Date</b>	<b>Marketing End Date</b>
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OTC Monograph Drug M017

09/01/2024

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

Revised: 9/2024

AVADIM HOLDINGS, INC.