THERAWORX PAIN RELIEF ROLL-ON WITH LIDOCAINE FOR DIABETICS-
lidocaine hydrochloride liquid
AVADIM HOLDINGS, INC.

Theraworx Pain Relief Roll-On with Lidocaine for Diabetics

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.

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

Package Labeling:

THERAWORX PAIN RELIEF ROLL-ON WITH LIDOCAINE FOR DIABETICS

lidocaine hydrochloride liquid

Product Information

Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:61594-030
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

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

Inactive Ingredients

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

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:61594-030-00	74 mL in 1 BOTTLE, WITH APPLICATOR; Type 0: Not a Combination Product	06/01/2024	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M017	06/01/2024	

Labeler - AVADIM HOLDINGS, INC. (118512488)

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