

## **LIDOCAINE- lidocaine 4% cream**

### **AvKARE**

*Disclaimer: Most OTC drugs are not reviewed and approved by FDA, however they may be marketed if they comply with applicable regulations and policies. FDA has not evaluated whether this product complies.*

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### **Lidocaine 4% Cream**

#### **Active Ingredient:**

Lidocaine 4% w/w

#### **Purpose**

Topical anesthetic

#### **Uses**

temporarily relieves pain and itching due to:

- minor cuts
- minor scrapes
- sunburn
- minor skin irritations
- minor burns
- insect bites

#### **WARNINGS**

**For external use only.**

#### **When using this product**

- do not use in or near the eyes
- do not use in large quantities, particularly over raw surfaces or blistered areas

#### **Stop use and ask doctor if**

- Allergic reaction occurs
- condition worsens or does not improve within 7 days
- symptoms clear up and return within a few days
- redness, irritation, swelling, pain or other symptoms begin or increase

#### **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 and older: Apply externally to the affected area up to 3-4 times daily.
- Children under 2 years of age: Consult a doctor.

**Other Information**

Store at USP controlled room temperature 20-25 degC (68-77 deg.F).

**Inactive ingredients**

Cetyl alcohol, citric acid, glycerin, glyceryl stearate SE, mineral oil, PEG-100 stearate, phenoxyethanol, purified water, stearyl alcohol, white petrolatum, xanthan gum



## LIDOCAINE

lidocaine 4% cream

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:42291-399
<b>Route of Administration</b>	TOPICAL		

Active Ingredient/Active Moiety				
Ingredient Name			Basis of Strength	Strength
LIDOCAINE (UNII: 98PI200987) (LIDOCAINE - UNII:98PI200987)			LIDOCAINE	4 g in 100 g
Inactive Ingredients				
Ingredient Name				Strength
PHENOXYETHANOL (UNII: HIE492ZZ3T)				
MINERAL OIL (UNII: T5L8T28FGP)				
GLYCERYL STEARATE SE (UNII: FCZ5MH785I)				
GLYCERIN (UNII: PDC6A3C0OX)				
PEG-100 STEARATE (UNII: YD01N1999R)				
XANTHAN GUM (UNII: TTV12P4NEE)				
WATER (UNII: 059QF0KO0R)				
CETYL ALCOHOL (UNII: 936JST6JCN)				
STEARYL ALCOHOL (UNII: 2KR89I4H1Y)				
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)				
PETROLATUM (UNII: 4T6H12BN9U)				
Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:42291-399-30	1 in 1 CARTON	07/10/2018	
1		30 g in 1 TUBE; Type 0: Not a Combination Product		
Marketing Information				
Marketing Category		Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final		part348	07/10/2018	

**Labeler -** AvKARE (796560394)