

LIDOCAINE- lidocaine 4% cream
AvKARE

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

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:42291-399
Route of Administration	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)	
CETYL ALCOHOL (UNII: 936JST6JCN)	
GLYCERIN (UNII: PDC6A3C0OX)	
PEG-100 STEARATE (UNII: YD01N1999R)	
XANTHAN GUM (UNII: TTV12P4NEE)	
WATER (UNII: 059QF0KO0R)	
STEARYL ALCOHOL (UNII: 2KR89I4H1Y)	
PETROLATUM (UNII: 4T6H12BN9U)	
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	

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 Drug	M017	07/10/2018	

Labeler - AvKARE (796560394)