THE DAVINCI COMPANY- lidocaine cream
The Davinci Company

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.

The DaVinci Company Lidocaine Ointment, USP 5%

Active Ingredient

Lidocaine 0.5%

Lidocaine 0.5% ..... Pain Reliever

Temporary relief of pain and itching due to

- sunburn - minor burn - insect bites - minor cuts - scraps

Warnings

For external use only

When using this product keep out of eyes

Rinse with warter to remove

Sop use and ask a doctor

system persist for more than 7 days.

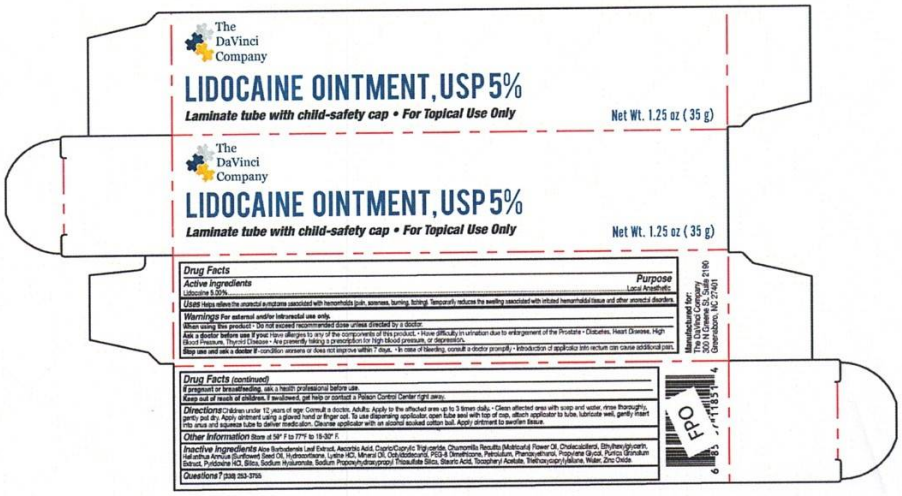
Keep out of reach of children. If product is swallowed, get medical help or contact a poison control center right away.

Direction

Adults and children 2 years and older: aooly to affected area not more that 3-4 times a day

Children under 2 years of age: consult a physician.

Inactive Ingredients: Aloe Barbadensis Leaf Extract, Carbomer, Diazolidinyl Urea, Disodium EDTA, Glycerin, Isopropyl Alcohol, Menthol, Polysorbate 80, Propylene Glycol, Triethanolamine, Water, Yellow 5.



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lidocaine cream

Product Information

Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:82951-001
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
LIDOCAINE HYDROCHLORIDE (UNII: V13007Z41A) (LIDOCAINE - UNII:98PI200987)	LIDOCAINE HYDROCHLORIDE ANHYDROUS	5 g in 100 g

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
ASCORBIC ACID (UNII: PQ6CK8PD0R)	
LYSINE HYDROCHLORIDE (UNII: JNJ23Q2COM)	
TRICAPRYLIN (UNII: 6P92858988)	
CHOLECALCIFEROL (UNII: 1C6V77QF41)	
SUNFLOWER OIL (UNII: 3W1JG795YI)	
CHAMOMILE FLOWER OIL (UNII: 60F80Z61A9)	
PUNICA GRANATUM ROOT BARK (UNII: CLV24I3T1D)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
SODIUM PROPOXYHYDROXYPROPYL THIOSULFATE SILICA (UNII: 208G222332)	
TRIETHOXYCAPRYLYLSILANE (UNII: LDC331P08E)	
ZINC OXIDE (UNII: SOI2LOH54Z)	
MINERAL OIL (UNII: T5L8T28FGP)	
OCTYLDODECANOL (UNII: 461N1O614Y)	
ETHYLHEXYLGLYCERIN (UNII: 147D247K3P)	
HYDROCORTISONE (UNII: W4X0X7BPJ)	
PYRIDOXINE HYDROCHLORIDE (UNII: 68Y4CF58BV)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
PEG-8 DIMETHICONE (UNII: GIA7T764OD)	
PETROLATUM (UNII: 4T6H12BN9U)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
HYALURONATE SODIUM (UNII: YSE9PPT4TH)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:82951-001-01	35 g in 1 TUBE; Type 0: Not a Combination Product	10/25/2022	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part348	10/25/2022	

Labeler - The Davinci Company (118425254)

Establishment

Name	Address	ID/FEI	Business Operations
Inspec Solutions LLC.		081030372	manufacture(82951-001)

Revised: 10/2022 The Davinci Company