CBD PAIN CREAM- lidocaine cream NATURES ORGANICS LLC

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.

Drug Facts

Active Ingredient

Lidocaine 4%

Purpose

Topical analgesic

Uses

Temporarily relieves minor pain associated with:

.Arthritis .Sprains .Simple backache

.Bruises .Muscle strains .Cramps

Warnings

For external use only

When using this product

• Use only as directed, do not bandage tightly, avoid contact with eyes, do not apply to wounds or damaged skin, do not use in large quantities, particularly over raw surfaces or blistered areas.

Stop use and ask a doctor if

• condition worsens, symptoms persist for more than 7 days or symptoms clear up and occur again within a few days.

Keep out of reach of children

If swallowed, get medical help or contact a Poison Control Center right away

Directions

- Adults and children 12 years of age and older: apply to the affected area not more than 3 to 4 times daily.
- Children under 12 years of age: Consult a doctor

Inactive ingrdients

Allantoin, Caprylic/Capric Triglyceride, Capsicum Annuum Fruit Powder, Calcium Disodium EDTA, Cannabis Sativa Extract Oil, Dimethicone, dI-alpha Tocopheryl Acetate, Ethyl Alcohol, Ethylhexylglycerin, Ethylhexyl Sterate, Fragrance, Glycerin, Phenoxyethanol, Polysorbate 80, Propanediol, Propylene Glycol, Purified Water, Simethicone, Sodium Polyacrylate, Trideceth-6, Vitis Vinifera (Grape) Seed oil, Xanthan Gum.

Principal Display Panel

NDC 73332-001-01

FOR EXTERNAL USE ONLY

CBD Pain Cream

+ Lidocaine



CBD PAIN CREAM

lidocaine cream

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:73332-001
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
LIDO CAINE (UNII: 98PI200987) (LIDO CAINE - UNII:98PI200987)	LIDOCAINE	40 mg in 1 mL	

Inactive Ingredients	
Ingredient Name	Strength
ALLANTO IN (UNII: 344S277G0Z)	

TRICAPRIN (UNII: O1PB8EU98M)	
PAPRIKA (UNII: X72Z47861V)	
EDETATE CALCIUM DISO DIUM ANHYDRO US (UNII: 8U5D0 34955)	
CANNABIS SATIVA SEED (UNII: QE567Z26NG)	
DIMETHICO NE (UNII: 92RU3N3Y1O)	
.ALPHATO COPHEROL ACETATE, DL- (UNII: WR1WPI7EW8)	
ALCOHOL (UNII: 3K9958V90M)	
ETHYLHEXYLGLYCERIN (UNII: 147D247K3P)	
ETHYLHEXYL STEARATE (UNII: EG3PA2K3K5)	
GLYCERIN (UNII: PDC6A3C0OX)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
POLYSORBATE 80 (UNII: 6OZP39ZG8H)	
PROPANEDIOL (UNII: 5965N8W85T)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
WATER (UNII: 059QF0KO0R)	
SODIUM POLYACRYLATE (2500000 MW) (UNII: 05I15JNI2J)	
TRIDECETH-6 (UNII: 3T5PCR2H0C)	
GRAPE SEED OIL (UNII: 930 MLC8 XGG)	
XANTHAN GUM (UNII: TTV12P4NEE)	

l	Packaging				
l	# Item Code	Package Description	Marketing Start Date	Marketing End Date	
l	1 NDC:73332-001-01	74 mL in 1 TUBE; Type 0: Not a Combination Product	09/18/2019		

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part346	09/18/2019	

Labeler - NATURES ORGANICS LLC (117141162)

Establishment				
Name	Address	ID/FEI	Business Operations	
Ion Labs Inc		106499791	manufacture(73332-001)	

Revised: 10/2019 NATURES ORGANICS LLC