CBDAF TOPICAL GEL- lidocaine hydrochloride, menthol gel Prime Enterprises

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.

CBDaF CBD & Lidocaine Topical Gel

Active Ingredients

Lidocaine Hydrochloride 4%, Menthol 1%

Purpose

Topical Analgesic

Uses

Use for temporary relief of minor pain

Warnings

For external use only.

Do not use

On large areas of the body or on cut, irritated or swollen skin

On puncture wounds

For more than one week without consulting a doctor

When using this product

Use only as directed

Avoid contact with eyes and mucous membranes

Do not apply to skin folds

Do not apply to wounds or damaged, broken or irritated skin

Do not bandage tightly or apply local heat (such as heating pads) or a medicated patch to the area of use

Stop use and ask doctor if

condition worses

irriation develops

redness appears

symptoms persist for more than 7 days or clear up and occurs again within a few days

Kepp out of reach of children

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

If pregnant or breast-feeding

ask a health professional before use.

Directions

Adults and children over 12 years:

apply a thin layer to affected area every 6 to 8 hours, but no more than 3 to 4 times daily if product comes in contact hands, wash hands with soap and water children 12 years or younger: ask a doctor

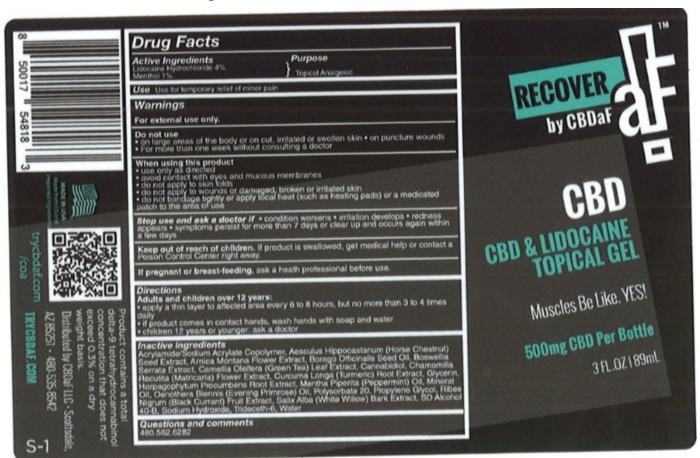
Inactive ingredients

Acrylamide/Sodium Acrylate Copolymer, Aesculus Hippocastanum (Horse Chestnut) Seed Extract, Arnica Montana Flower Extract, Borago Officinalis Seed Oil, Boswellia Serrata Extract, Camellia Oleifera (Green Tea) Leaf Extract, Cannabidiol, Chamomilla Recutita (Matricaria) Flower Extract, Curcuma Longa (Turmeric) Root Extract, Glycerin, Harpagophytum Procumbens Root Extract, Mentha Piperita (Peppermint) Oil, Mineral Oil, Oenothera Biennis (Evening Primrose) Oil, Polysorbate 20, Propylene Glycol, Ribes Nigrum (Black Currant) Fruit Extract, Salix Alba (White Willow) Bark Extract, SD Alcohol 40-B, Sodium Hydroxide, Trideceth-6, Water

Questions and comments

480.562.6282

CBDaF CBD & lidocaine Topical Gel



lidocaine hydrochloride, menthol gel

Product Information

Product TypeHUMAN OTC DRUGItem Code (Source)NDC:58443-0366

Route of Administration TOPICAL

Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
MENTHOL (UNII: L7T10EIP3A) (MENTHOL - UNII:L7T10EIP3A)	MENTHOL	9.62 mg in 1 mL	
LIDO CAINE HYDRO CHLO RIDE (UNII: V13007Z41A) (LIDO CAINE - UNII:98 PI200987)	LIDOCAINE HYDROCHLORIDE ANHYDROUS	38.48 mg in 1 mL	

Inactive Ingredients			
Ingredient Name	Strength		
ACRYLAMIDE (UNII: 20 R0 35 KLCI)			
SODIUM ACRYLATE (UNII: 7C98FKB43H)			
CAMELLIA O LEIFERA LEAF (UNII: 5077EL0C60)			
WATER (UNII: 059QF0KO0R)			
TRIDECETH-6 (UNII: 3T5PCR2H0C)			
CHAMO MILE (UNII: FGL3685T2X)			
MINERAL OIL (UNII: T5L8T28FGP)			
SO DIUM HYDRO XIDE (UNII: 55X0 4QC32I)			
HORSE CHESTNUT (UNII: 3C18L6RJAZ)			
PEPPERMINT OIL (UNII: AV092KU4JH)			
ARNICA MONTANA FLOWER (UNII: OZ0E5Y15PZ)			
HARPAGO PHYTUM PRO CUMBENS ROOT (UNII: 10 YM338 E89)			
SALIX ALBA BARK (UNII: 205MXS71H7)			
BORAGE SEED OIL (UNII: F8 XAG1755S)			
TURMERIC (UNII: 856 YO1Z64F)			
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)			
INDIAN FRANKINCENSE (UNII: 4PW41QCO2M)			
BLACK CURRANT (UNII: 9755T40 D11)			
ALCOHOL (UNII: 3K9958V90M)			
EVENING PRIMROSE OIL (UNII: 3Q9L08K71N)			
POLYSORBATE 20 (UNII: 7T1F30V5YH)			
CANNABIDIO L (UNII: 19 GBJ6 0 SN5)			
GLYCERIN (UNII: PDC6A3C0OX)			

Product Characteristics			
Color	white (White to Off White)	Score	
Shape		Size	
Flavor		Imprint Code	
Contains			
Contains			

Packaging				
# Item Code	Package Description	Marketing Start Date	Marketing End Date	
1 NDC:58443-0366-3	89 mL in 1 BOTTLE; Type 0: Not a Combination Product	05/01/2019		
Marketing Information				
Marketing Categor	ry Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
OTC monograph not fir	nal part348	05/01/2019		

Labeler - Prime Enterprises (101946028)

Registrant - Prime Enterprises (101946028)

Establishment			
Name	Address	ID/FEI	Business Operations
Prime Enterprises		10 19 46 0 28	manufacture(58443-0366), label(58443-0366), analysis(58443-0366), pack(58443-0366)

Revised: 10/2020 Prime Enterprises