CBD4 FREEZE PUMP VANISHING SCENT- lidocaine, menthol cream
HMP BRANDS, 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.

Active Ingredient **Purpose**

Lidocaine HCI USP 4%..... Topical anesthetic

Menthol USP 1 % ..... Topical analgesic

Use

Temporarily relieves 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.
- Read and follow all directions and warnings on this label.
- Rare cases of serious burns have been reported with products of this type.
- Do not bandage tightly or apply local heat (such as heating pads) to the area of use or use with a medicated patch.
- Avoid contact with eyes and mucous membranes.
- A transient burning sensation may occur upon application but generally disappears in several days.

Stop use and ask a doctor if

- condition worsens.
- redness is present.
- irritation develops.
- symptoms persist for more than 7 days or clear up and occur again within a few days.
- You experience signs of skin injury, such as pain, swelling, or blistering where the product was applied.

If pregnant or breast-feeding, ask a healthcare professional before use..

Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.

Directions

adults and children over 12 years:

- Apply a thin layer to affected area every 6 to 8 hours, not to exceed 3 applications in a 24 hour period.

- After applying, wash hands with soap and water

Children 12 years or younger: ask a doctor

Other information

- Store at 68-77°F (20-25°F) in a dry place
- Keep from freezing

Inactive ingredients

cetostearyl alcohol, citric acid, hemp extract(cannabidiol), light liquid paraffin, macrogol cetostearyl ether, methyl parahydroxybenzoate, peppermint oil, purified water, sodium citrate and white soft paraffin.

PRODUCT LABEL

CBD4 FREEZE PUMP VANISHING SCENT

lidocaine, menthol cream

Product Information

Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:80875-421
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
MENTHOL (UNII: L7T10EIP3A) (MENTHOL - UNII:L7T10EIP3A)	MENTHOL	1 g in 100 g

Inactive Ingredients

Ingredient Name	Strength
CETOSTEARYL ALCOHOL (UNII: 2DMT128M1S)	
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	
CANNABIDIOL (UNII: 19GBJ60SN5)	
LIGHT MINERAL OIL (UNII: N6K5787QVP)	
POLYOXYL 20 CETOSTEARYL ETHER (UNII: YRC528SWUY)	
METHYLPARABEN (UNII: A2I8C7HI9T)	
PEPPERMINT OIL (UNII: AV092KU4JH)	
WATER (UNII: 059QF0KO0R)	
SODIUM CITRATE (UNII: 1Q73Q2JULR)	
PETROLATUM (UNII: 4T6H12BN9U)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:80875-421-60	60 g in 1 TUBE; Type 0: Not a Combination Product	10/29/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part348	10/29/2020	

Labeler - HMP BRANDS, LLC (117688328)

Establishment

Name	Address	ID/FEI	Business Operations
HMP BRANDS, LLC		117688328	manufacture(80875-421)

Revised: 10/2020 HMP BRANDS, LLC