

COLDSORE BOMB- menthol ointment

Envisionate PSJ 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 ingredients

Menthol 1%

Purpose

External analgesic

Directions

- Adults and children 2 years of age and older: Apply to the affected area not more than 5 times daily.

Other Information

Store at room temperature 68 to 77°F (20 to 25°C).

Inactive Ingredients

Cocoa Butter, Coconut Oil, Croton Lechleri, Grapeseed Oil, Lanolin, Peppermint Oil, Tea Tree Oil

Packaging

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COLDSORE BOMB

menthol ointment

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:72883-020
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
MENTHOL (UNII: L7T10EIP3A) (MENTHOL - UNII:L7T10EIP3A)	MENTHOL	1 g in 100 g

Inactive Ingredients

Ingredient Name	Strength
LANOLIN (UNII: 7EV65EAW6H)	
COCOA BUTTER (UNII: 512OYT1CRR)	
COCONUT OIL (UNII: Q9L0O73W7L)	
GRAPE SEED OIL (UNII: 930MLC8XGG)	
PEPPERMINT OIL (UNII: AV092KU4JH)	
CROTON LECHLERI RESIN (UNII: GGG6W25C63)	
TEA TREE OIL (UNII: VIF565UC2G)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:72883-020-01	1 in 1 BOX	12/09/2019	
1		3.5 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 final	part346	12/09/2019	

Labeler - Envisionate PSJ LLC (116959523)**Registrant** - Envisionate PSJ LLC (116959523)**Establishment**

Name	Address	ID/FEI	Business Operations
Paket Corporation		007774730	manufacture(72883-020)