

BLISTER BALM- menthol 1% salve
Floratech Botanicals, 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.

External analgesic

Active Ingredients

Menthol 1%

Purpose

External Analgesic - cold sore or fever blister treatment

Uses:

For relief of pain and itching associated with cold sore and fever blister outbreaks.

Intense and immediate blocking of cold sore and fever blister symptoms.

Warnings

For external use only.

Keep out of reach of children.

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

keep out of reach of children. If swallowed get medical help or contact a poison control center immediately. (1-800-222-1222)

Stop use and ask doctor if condition worsen or if symptoms persist for more than 7 days or clear up and occur again within a few days.

When using this product avoid contact with the eyes

keep out of Reach of children. If swallowed, get medical help or contact a poison control center immediately. (1-800-222-1222)

Directions

- Adults and children 2 years of age and older. Apply to the affected area not more than 3 to 4 times daily.
- Children under 2 years of age: consult a doctor

Inactive Ingredients

camphor

clove (syzygium aromaticum) leaf oil

eucalyptus globulus leaf oil

hydrolyzed jojoba esters

isopropyl jojobate

jojoba (simmondsia chinensis) esters

jojoba alcohols

lemon balm (melissa officinalis) oil

peppermint (menthe piperita) oil

rose geranium (pelargonium graveolens) oil



BLISTER BALM

menthol 1% salve

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:70996-003
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
EUCALYPTUS GLOBULUS LEAF (UNII: S546YLV6E6)	
HYDROLYZED JOJOBA ESTERS (ACID FORM) (UNII: UDR641JW8W)	
LEMON BALM OIL (UNII: MJ76269K9S)	
ALPROSTADIL ISOPROPYL ESTER (UNII: 8THV3YDD6A)	
CLOVE LEAF OIL (UNII: VCA5491KVF)	
PELARGONIUM ROSEUM OIL (UNII: XSN2Q85DC6)	
PEPPERMINT OIL (UNII: AV092KU4JH)	
HYDROGENATED JOJOBA OIL (UNII: 7F674YQ5SO)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:70996-003-01	2.6 g in 1 TUBE; Type 0: Not a Combination Product	12/21/2016	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part348	12/21/2016	

Labeler - Floratech Botanicals, LLC (805985686)

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Floratech Botanicals, LLC