

ULTRA STRENGTH PAIN RELIEF BALM- camphor menthol ointment ointment
Suzhou Vastech Medical Technology Co., Ltd

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 ingredients Purpose

Camphor 11%..... Topical analgesic
Menthol 11%..... Topical analgesic

Uses

For temporary relief of minor aches and pains of muscles and joints associated with over-exertion, simple backache, arthritis, strains, and sprains.

Warnings

For external use only.

When using this product

- Avoid contact with the eyes and mucous membranes
- Do not apply to open wounds or damaged skin
- Do not bandage or use heating pad

Stop use and ask a doctor if

- Condition worsens
- Severe skin irritation occurs
- Pain persists for more than seven days
- Pain clears up and then recurs a few days later

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 immediately.

Directions

- Rub well on the affected area. Repeat 3 to 4 times daily.
- For children 2-12 years, consult a doctor before use.

Other information

This product may cause allergic reaction in some individuals. Test on small area before use.

Inactive ingredients

cajuput oil, clove oil, dementholized mint oil, paraffin petrolatuma

Distributed by:

MCURE HEALTH SOLUTIONS INC.

20819 Currier Rd #200

City of Industry, CA 91789

Made in China



ULTRA STRENGTH PAIN RELIEF BALM

camphor menthol ointment ointment

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:71183-320
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
MENTHOL (UNII: L7T10EIP3A) (MENTHOL - UNII:L7T10EIP3A)	MENTHOL	11 g in 100 g
CAMPHOR (SYNTHETIC) (UNII: 5TJD82A1ET) (CAMPHOR (SYNTHETIC) - UNII:5TJD82A1ET)	CAMPHOR (SYNTHETIC)	11 g in 100 g

Inactive Ingredients

Ingredient Name	Strength
PETROLATUM (UNII: 4T6H12BN9U)	
PARAFFIN (UNII: I9O0E3H2ZE)	
CAJUPUT OIL (UNII: J3TO6BUQ37)	
CLOVE OIL (UNII: 578389D6D0)	

Product Characteristics

Color	white	Score	
Shape		Size	
Flavor		Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:71183-320-18	18 g in 1 BOTTLE; Type 0: Not a Combination Product	03/20/2017	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part348	03/20/2017	

Labeler - Suzhou Vastech Medical Technology Co., Ltd (543772485)

Registrant - Suzhou Vastech Medical Technology Co., Ltd (543772485)

Establishment

Name	Address	ID/FEI	Business Operations
Suzhou Vastech Medical Technology Co., Ltd		543772485	manufacture(71183-320)