

BLUE ICE FERMENTED COD LIVER OIL CALM BALM- camphor, menthol, eucalyptus oil rub salve

ABS Corporation

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.

Blue Ice Fermented Cod Liver Oil Calm Balm

ACTIVE INGREDIENTS:

Active Ingredients	Purpose
Camphor (2.63%)	Topical Analgesic
Eucalyptus Oil (3.5%)	Topical Analgesic
Menthol (0.74%)	Topical Analgesic

PURPOSE:

Active Ingredients	Purpose
Camphor (2.63%)	Topical Analgesic
Eucalyptus Oil (3.5%)	Topical Analgesic
Menthol (0.74%)	Topical Analgesic

Keep Out of Reach of Children.

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

Uses:

- on muscles and joints
- temporarily relieves minor aches and pains

Warnings:

For external use only

- avoid contact with eyes.

DO NOT USE

- by mouth
- with tight bandages
- in nostrils
- on wounds or damaged skin
- in or near eyes
- Do not apply to infected or open wounds.

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When using this product:

DO NOT

- heat

- microwave
- add to hot water or any container containing hot water. This may cause splattering and result in burns.

Stop Use and Ask Doctor if:

- muscle aches and pains persist more than 7 days or come back
- if irritation occurs, discontinue use

If pregnant or breast-feeding:

ask a health professional before use.

Directions:

Directions:

Adults and children 2 years and over:

- rub on sore aching muscles
- not more than three times per 24 hours or as directed by doctor

INACTIVE INGREDIENTS:

Shea Butter, Blue Breeze Organic Coconut Oil,
 X-Factor Gold High Vitamin Butter Oil, White Bees Wax,
 Blue Ice Fermented Cod Liver Oil, Cranberry Seed Oil,
 Peppermint Oil, Rosemary Oil.

Contains: Cod, milk, shea nut, and coconut.

NDC 18472-175-01

BLUE ICE™

FERMENTED COD LIVER OIL

CALM BALM

A Deep Muscle and Joint Rub

With:

Blue Ice™ Fermented Cod Liver Oil - High Vitamin Butter Oil

Blue Breeze™ Organic Virgin Coconut Oil - Wild Crafted Shea Butter



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 camphor, menthol, eucalyptus oil rub salve

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:18472-175
Route of Administration	Topical		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
CAMPHOR (NATURAL) (UNII: N20HL7Q941) (CAMPHOR (NATURAL) - UNII:N20HL7Q941)	CAMPHOR (NATURAL)	1.30 g in 49.5 g
EUCALYPTUS OIL (UNII: 2R04ONI662) (EUCALYPTUS OIL - UNII:2R04ONI662)	EUCALYPTUS OIL	1.73 g in 49.5 g
MENTHOL (UNII: L7T10EIP3A) (MENTHOL - UNII:L7T10EIP3A)	MENTHOL	0.37 g in 49.5 g

Inactive Ingredients

Ingredient Name	Strength
SHEA BUTTER (UNII: K49155WL9Y)	15.59 g in 49.5 g
COCONUT OIL (UNII: Q9L0O73W7L)	12.87 g in 49.5 g
OLEIC ACID (UNII: 2UM9U37CP)	7.43 g in 49.5 g
WHITE WAX (UNII: 7G1J5DA97F)	5.45 g in 49.5 g
COD LIVER OIL (UNII: BBL281NWFQ)	3.86 g in 49.5 g
CRANBERRY SEED OIL (UNII: 73KDS3BW5E)	10.59 g in 49.5 g
PEPPERMINT OIL (UNII: AV092KU4JH)	0.13 g in 49.5 g
ROSEMARY OIL (UNII: 8LGU7VM393)	0.01 g in 49.5 g

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:18472-175-01	49.5 g in 1 JAR	09/13/2011	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part348	09/01/2011	

Labeler - ABS Corporation (048022727)

Registrant - ABS Corporation (048022727)

Establishment

Name	Address	ID/FEI	Business Operations
ABS Corporation		048022727	api manufacture(18472-175) , pack(18472-175) , label(18472-175)