

ZIMS MAX FREEZE PRO FORMULA- menthol, unspecified form gel
KOBAYASHI Healthcare International, Inc.

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.

ZIM'S™ MAX FREEZE
PRO FORMULA

Drug Facts

Active ingredient

Menthol 7%

Purpose

Topical Analgesic

Uses

For the temporary relief of minor aches and pains of muscles and joints associated with:

- Simple backache
- Arthritis
- Strains
- Bruises
- Sprains

Warnings

For external use only

Rare cases of burns have been reported with products of this type

Flammable: Keep away from fire or flame and heated surfaces

Do not use

- if you are allergic to any ingredient in this product
- on open wounds, damaged or irritated skin
- with a heating pad or TENS device
- after expiration date

When using this product

- may cause a burning sensation wherever it is applied, but is usually mild and gradually lessens over time
- do not bandage tightly
- do not use otherwise than as directed
- avoid contact with eyes or mucous membranes

Stop use and ask a doctor if

- burning sensation is painful and persistent
- condition worsens
- rash, itching, redness or excessive irritation of the skin develops

- symptoms persist for more than 7 days
- symptoms clear up and occur again within a few days

If pregnant or breast-feeding, ask a health 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 12 years of age and over:

- apply to affected area using roller ball not more than 4 times daily
- massage painful area until absorbed into skin
- wash hands after each use with cold water

Children under 12 years of age:

- consult a doctor

Other information

- store in a cool place away from direct sunlight
store with cap closed tightly

Inactive ingredients

¹Aloe Barbadensis Leaf Extract, Ammonium Acryloyldimethyltaurate/VP Copolymer, Arnica Extract, Isopropyl Alcohol, Propylene Glycol, Tea Tree Oil, Vanillyl Butyl Ether, Water.

¹ Symbol before the ingredient indicates certified organic.

Consumer Comments Call:
1-800-432-8629

Distributed by: **KOBAYASHI
Consumer Products, LLC**
P.O. Box 1191, Dalton, GA 30722

PRINCIPAL DISPLAY PANEL - 85 g Bottle Label

EXTRA STRENGTH

ZIM'S™

MAX-
FREEZE

PRO FORMULA

- LONGER LASTING* -
PAIN RELIEF

- FAST ACTING
- LONG LASTING
- VANISHING SCENT

COLD THERAPY
COOLING ROLL-ON

with 7% Menthol

Net Wt 3oz (85g)

*compared to original

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with 7% Menthol

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ZimsUSA.com
14039.002

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Share your feedback at: feedback.ZimsUSA.com for a chance to win an assortment of Kobayashi products.
Made in U.S.A. using domestic and imported materials
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ZIMS MAX FREEZE PRO FORMULA

menthol, unspecified form gel

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:54273-007
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
MENTHOL, UNSPECIFIED FORM (UNII: L7T10EIP3A) (MENTHOL, UNSPECIFIED FORM - UNII:L7T10EIP3A)	MENTHOL, UNSPECIFIED FORM	70 mg in 1 g

Inactive Ingredients

Ingredient Name	Strength
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
ARNICA MONTANA (UNII: O80TY208ZW)	

VANILLYL BUTYL ETHER (UNII: S2ULN37C9R)	
WATER (UNII: 059QF0K00R)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
TEA TREE OIL (UNII: VIF565UC2G)	
ISOPROPYL ALCOHOL (UNII: ND2M416302)	
HYDROXYPROPYL CELLULOSE, UNSPECIFIED (UNII: 9XZ8H6N6OH)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:54273-007-01	85 g in 1 BOTTLE, WITH APPLICATOR; Type 0: Not a Combination Product	08/01/2018	
2	NDC:54273-007-02	102 g in 1 BOTTLE, WITH APPLICATOR; Type 0: Not a Combination Product	02/01/2019	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH NOT FINAL	part348	08/01/2018	

Labeler - KOBAYASHI Healthcare International, Inc. (156391729)

Revised: 5/2019

KOBAYASHI Healthcare International, Inc.