

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

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 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, Hydroxypropylcellulose, 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 - 113 g Tube Label

EXTRA STRENGTH

ZIM'S™
MAX-
FREEZE

PRO FORMULA

- LONGER LASTING* -
PAIN RELIEF

- FAST ACTING
- LONG LASTING
- VANISHING SCENT

COLD THERAPY
COOLING GEL
with 7% Menthol

Net Wt 4oz (113g)

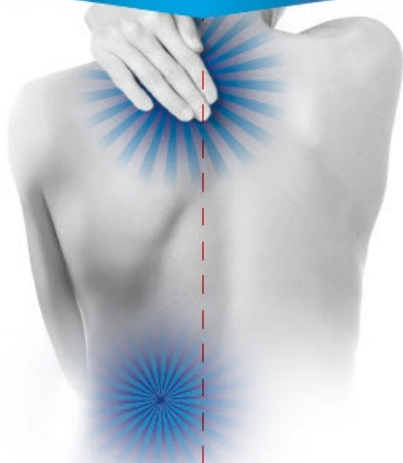
*compared to original

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ZimsUSA.com 14040.002



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ZIMS MAX FREEZE PRO FORMULA

menthol, unspecified form gel

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:54273-006
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 WHOLE (UNII: O80TY208ZW)	
VANILLYL BUTYL ETHER (UNII: S2ULN37C9R)	
AMMONIUM ACRYLOYLDIMETHYLTAURATE/VP COPOLYMER (UNII: W59H9296ZG)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
TEA TREE OIL (UNII: VIF565UC2G)	
ISOPROPYL ALCOHOL (UNII: ND2M416302)	
HYDROXYPROPYL CELLULOSE, UNSPECIFIED (UNII: 9XZ8H6N6OH)	
WATER (UNII: 059QF0KO0R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:54273-006-01	113 g in 1 TUBE; Type 0: Not a Combination Product	07/01/2018	
2	NDC:54273-006-02	136 g in 1 TUBE; Type 0: Not a Combination Product	02/01/2019	
3	NDC:54273-006-03	5 g in 1 PACKET; Type 0: Not a Combination Product	01/01/2019	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph drug	M017	07/01/2018	

Labeler - KOBAYASHI Healthcare International, Inc. (156391729)

Registrant - KOBAYASHI America Manufacturing, LLC (079852150)

Establishment

Name	Address	ID/FEI	Business Operations
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Revised: 11/2023

KOBAYASHI Healthcare International, Inc.