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 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



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	MENTHOL, UNSPECIFIED	70 mg
FORM - UNII:L7T10EIP3A)	FORM	in 1 g

Inactive Ingredients			
Ingredient Name	Strength		
ALOE VERA LEAF (UNII: ZY81Z83H0X)			
ARNICA MONTANA WHOLE (UNII: O80TY208ZW)			
VANILLYL BUTYL ETHER (UNII: S2ULN37C9R)			
WATER (UNII: 059QF0KO0R)			
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)			
TEA TREE OIL (UNII: VIF565UC2G)			
ISOPROPYL ALCOHOL (UNII: ND2M416302)			
HYDROXYPROPYL CELLULOSE, UNSPECIFIED (UNII: 9XZ 8H6N6OH)			

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:54273- 007-01	85 g in 1 BOTTLE, WTH 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 drug	M017	08/01/2018	

Labeler - KOBAYASHI Healthcare International, Inc. (156391729)

Registrant - KOBAYASHI America Manufacturing, LLC (079852150)

Establishment				
Name	Address	ID/FEI	Business Operations	
KOBAYASHI America Manufacturing, LLC		079852150	PACK(54273-007), LABEL(54273-007)	

Revised: 11/2023 KOBAYASHI Healthcare International, Inc.