# EZ MASSAGER 4 EXTRA STRENGTH- menthol gel BlackPort Distribution

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.

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- Massage into painful area until thoroughly absorbed into skin
- Repeat as necessary but not more than 3 to 4 times per day

WARNING: For external use only

DO NOT USE: On wounds or damaged skin with a heating pad

#### ASK A DOCTOR BEFORE USE IF:

- You have redness over the affected area
- Conditions worsen or sypmtoms persist for more than 7 days
- Symptons clear up and occur again within a few days
- Excessive skin irritation occurs
- You are pregnant or breast feeding

Ginkgo biloba leaf oil

Panax ginseng root oil

Arnica Montana

Ethylhexylglycerin

Thymus vulgaris leaf

Water

Alcohol

Dimethicone 200

Sodium polyacrylate (8000 mw)

Instant relief for:

Arthritis

Backache

**Bruises** 

Cramps

**Sprains** 

Strains

## WHEN USING THIS PRODUCT:

- Avoid contact with eves or mucous membranes
- Do not bandage tightly

### Topical Analgesic

KEEP OUT OF REACH OF CHILDREN: If swallowed, get medical help or contact a Poison Control Center right away.

Menthol, 2%





## EZ MASSAGER 4 EXTRA STRENGTH

menthol gel

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:71555-004
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
MENTHOL (UNII: L7T10EIP3A) (MENTHOL - UNII:L7T10EIP3A)	MENTHOL	4 g in 100 mL	

Inactive Ingredients			
Ingredient Name	Strength		
THYMUS VULGARIS LEAF (UNII: GRX3499643)			
GINKGO BILOBA LEAF OIL (UNII: Y5967KO1JH)			
ETHYLHEXYLGLYCERIN (UNII: 147D247K3P)			
ALCOHOL (UNII: 3K9958V90M)			
DIMETHICO NE 200 (UNII: RGS4T2AS00)			
SODIUM POLYACRYLATE (8000 MW) (UNII: 285CYO341L)			
PANAX GINSENG ROOT OIL (UNII: P9T4K47OM0)			

# ARNICA MONTANA (UNII: O80TY208ZW) WATER (UNII: 059QF0KO0R)

Product Characteristics		
Color		Score
Shape	FREEFORM (Gel)	Size
Flavor		Imprint Code
Contains		

ı	Pa	ackaging			
ı	#	Item Code	Package Description	<b>Marketing Start Date</b>	<b>Marketing End Date</b>
ı	1	NDC:71555-004-02	100 mL in 1 CANISTER; Type 0: Not a Combination Product	08/01/2017	
ı					

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part348	08/01/2017	

# Labeler - BlackPort Distribution (539179900)

## **Registrant -** EZM Distributions, LLC (080627876)

Establishment				
Name	Address	ID/FEI	Business Operations	
Cunningpac CC		539075187	manufacture(71555-004)	

Revised: 11/2017 BlackPort Distribution