

## **EZ MASSAGER 4 EXTRA STRENGTH- menthol gel**

**CunningPac**

*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 symptoms persist for more than 7 days
- \* Symptoms 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

THYMUS VULGARIS LEAF

WATER

ALCOHOL

SODIUM POLYACRYLATE (8000 MW)

DIMETHICONE 200

ETHYLHEXYLGLYCERIN

Instant relief for:

Arthritis

Backache

Bruises

Cramps

Sprains

Strains

WHEN USING THIS PRODUCT:

- \* Avoid contact with eyes 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 %

**EXTRA STRENGTH 4% MENTHOL**  
EZ GRIP - For a deeper massage. No mess.

**DRUG FACTS:**  
**ACTIVE INGREDIENTS:** Menthol 4%.....**PURPOSE:** Topical analgesic  
**INACTIVE INGREDIENTS:** Ginkgo biloba leaf oil, Panax ginseng root oil, Arnica Montana, Ethylhexylglycerin, Thymus vulgaris leaf, Water, Alcohol, Dimethicone 200, Sodium polyacrylate (8000 mw)  
**QUESTIONS/COMMENTS?** info@ezmassager.com

**DIRECTIONS:**  
Adults and children over 12 years  
• Massage into painful area until thoroughly absorbed into skin  
• Repeat as necessary but not more than 3 to 4 times per day  
• Children under 12 years of age, consult a doctor

**INSTANT RELIEF FOR:**

- Arthritis •
- Backache •
- Bruises •
- Cramps •
- Sprains •
- Strains •



**Patented Dual Massage Roller**  
Instantly soothes muscle & joint pain

**Arnica & 4% Menthol Gel**  
Long lasting relief for aches, pains & swelling

**WARNING:** For external use only. KEEP OUT OF REACH OF CHILDREN. If swallowed, get medical help or contact a Poison Control Center right away.

**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 symptoms persist for more than 7 days • Symptoms clear up and occur again within a few days • Excessive skin irritation occurs • You are pregnant or breast feeding **WHEN USING THIS PRODUCT:** Avoid contact with eyes or mucous membranes • Do not bandage tightly

Distributed by Ezze Massager:  
1 Riverhorse Close, Riverhorse Valley, Durban, 4001, South Africa  
Tel: 082 901 5600 | © 2017 Ezze Massager | ezze-massager.co.za



## EZ MASSAGER 4 EXTRA STRENGTH

menthol gel

### Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:71633-004
Route of Administration	TOPICAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
MENTHOL (UNII: L7T10EIP3A) (MENTHOL - UNII:L7T10EIP3A)	MENTHOL	2 g in 100 mL

### Inactive Ingredients

Ingredient Name	Strength
GINKGO BILOBA LEAF OIL (UNII: Y5967KO1JH)	
SODIUM POLYACRYLATE (8000 MW) (UNII: 285CYO341L)	
WATER (UNII: 059QF0KO0R)	
ALCOHOL (UNII: 3K9958V90M)	
DIMETHICONE 200 (UNII: RGS4T2AS00)	
ARNICA MONTANA (UNII: O80TY208ZW)	
ETHYLHEXYLGLYCERIN (UNII: 147D247K3P)	
PANAX GINSENG ROOT OIL (UNII: P9T4K47OM0)	
THYMUS VULGARIS LEAF (UNII: GRX3499643)	

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:71633-004-01	12 in 1 CARTON	08/01/2017	
1		12 mL in 1 CANISTER; Type 0: Not a Combination Product		

## Marketing Information

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

**Labeler** - CunningPac (539075187)

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

## Establishment

Name	Address	ID/FEI	Business Operations
CunningPac		539075187	manufacture(71633-004)

Revised: 8/2017

CunningPac