# EQUATE COLD THERAPY PAIN RELIEVING ROLL-ON ANALGESIC- menthol, unspecified form gel Wal-Mart Stores, 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.

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#### Equate<sup>™</sup> Cold Therapy Pain Relieving Gel Roll-on Topical Analgesic

#### **Drug Facts**

#### **Active ingredient**

Menthol 4%

#### Purpose

Topical analgesic

#### Uses

for the temporary relief of minor aches and pains of muscles and joints associated with simple backache, arthritis, strains, bruises, and sprains

### Warnings

For external use only

Ask a doctor before use if you have sensitive skin

#### When using this product

- Avoid contact with eyes
- Do not apply to wounds or damaged skin
- Do not use with other ointments, creams sprays or liniments
- Do not apply to irritated skin or if excessive irritation develops
- Do not bandage tightly
- Wash hands after use with cool water
- Do not use with heating pads or heating devices

**Stop use and consult a doctor if** condition worsens, or if symptoms persist for more than 7 days or clear up and occur again within a few days.

### Flammable

keep away from excessive heat or open flame

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 (1-800-222-1222) immediately.

### Directions

- Adults and children 2 years of age and older: Apply to affected area not more than 3-4 times daily.
- Children under 2 years of age: Consult a doctor.

# Other information

Store in a cool dry place with lid closed tightly

## Inactive ingredients

aloe barbadensis leaf juice, arnica montana flower extract, blue 1, boswellia serrata resin extract, calendula officinalis flower extract, camellia sinensis leaf extract, camphor, carbomer, glycerin, isopropyl alcohol, isopropyl myristate, silica, sodium hydroxide, tocopheryl acetate, water, yellow 5.

## **Questions or comments?**

1-888-287-1915

DISTRIBUTED BY: Walmart Inc., Bentonville, AR 72716

# PRINCIPAL DISPLAY PANEL - 74 mL Bottle Label

NDC 79903-022-01

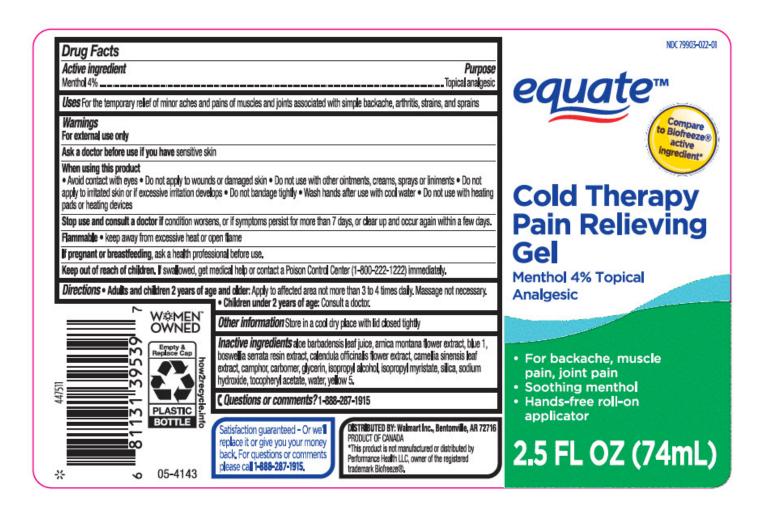
equate™

Compare to Biofreeze<sup>®</sup> active ingredient\*

Cold Therapy Pain Relieving Gel

Menthol 4% Topical Analgesic

- For backache, muscle pain, joint pain
- Soothing menthol
- Hands-free roll-on applicator



# EQUATE COLD THERAPY PAIN RELIEVING ROLL-ON ANALGESIC

menthol, unspecified form gel

| Product Information   |                 |   |                         |         |                  |
|---|-----------------|---|-------------------------|---------|------------------|
| Product Type  | HUMAN OTC DRUG  | HUMAN OTC DRUG Item Code (Source) NDC:79903-0 |                         | 03-022  |                  |
| Route of Administration   | TOPICAL         |   |                         |         |                  |
|   |                 |   |                         |         |                  |
| Active Ingredient/Active  | Moiety          |   |                         |         |                  |
| Ingredient Name   |                 |   | Basis of St             | trength | Strength         |
| <b>MENTHOL, UNSPECIFIED FORM</b> (UNII: L7T10EIP3A) (MENTHOL, UNSPECIFIED FORM - UNII:L7T10EIP3A) |                 |   | MENTHOL,<br>UNSPECIFIED | FORM    | 40 mg<br>in 1 mL |
|   |                 |   |                         |         |                  |
| Inactive Ingredients  |                 |   |                         |         |                  |
|   | Ingredient Name |   |                         | S       | Strength         |
| ALOE VERA LEAF (UNII: ZY81Z83   | H0X)            |   |                         |         |                  |
| Arnica Montana Flower (UNII: O  | Z0E5Y15PZ)      |   |                         |         |                  |
| FD&C BLUE NO. 1 (UNII: H3R47K   | מחדר            |   |                         |         |                  |

| INDIAN FRANKINCENSE (UNII: 4PW41QCO2M)                    |  |
|---|--|
| Calendula Officinalis Flower (UNII: P0M7O4Y7YD)           |  |
| GREEN TEA LEAF (UNII: W2ZU1RY8B0)                         |  |
| CAMPHOR (SYNTHETIC) (UNII: 5TJD82A1ET)                    |  |
| CARBOMER HOMOPOLYMER, UNSPECIFIED TYPE (UNII: 0A5MM307FC) |  |
| Glycerin (UNII: PDC6A3C0OX)                               |  |
| Isopropyl Alcohol (UNII: ND2M416302)                      |  |
| Isopropyl Myristate (UNII: 0RE8K4LNJS)                    |  |
| SILICON DIOXIDE (UNII: ETJ7Z6XBU4)                        |  |
| Sodium Hydroxide (UNII: 55X04QC32I)                       |  |
| .ALPHATOCOPHEROL ACETATE, DL- (UNII: WR1WPI7EW8)          |  |
| Water (UNII: 059QF0KO0R)                                  |  |
| FD&C YELLOW NO. 5 (UNII: I753WB2F1M)                      |  |
|   |  |

### **Product Characteristics**

| Color    | GREEN | Score        |
|----------|-------|--------------|
| Shape    |       | Size         |
| Flavor   |       | Imprint Code |
| Contains |       |              |

# Packaging

| # | Item Code            | Package Description  | Marketing Start<br>Date | Marketing End<br>Date |
|---|----------------------|--|-------------------------|-----------------------|
|   | NDC:79903-<br>022-01 | 74 mL in 1 BOTTLE, WTH APPLICATOR; Type 0: Not a Combination Product | 01/14/2021              |                       |

# **Marketing Information**

| Marketing Category         | Application Number or Monograph<br>Citation | Marketing Start<br>Date | Marketing End<br>Date |
|----------------------------|---|-------------------------|-----------------------|
| OTC MONOGRAPH NOT<br>FINAL | part348                                     | 01/14/2021              |                       |
|                            |   |                         |                       |

# Labeler - Wal-Mart Stores, Inc. (051957769)

Registrant - Garcoa, Inc. (036464697)

| Establishment         |         |           |                            |  |  |
|-----------------------|---------|-----------|----------------------------|--|--|
| Name                  | Address | ID/FEI    | <b>Business Operations</b> |  |  |
| Sigan Industries INC. |         | 255106239 | MANUFACTURE(79903-022)     |  |  |

Revised: 2/2023

Wal-Mart Stores, Inc.