

FREEZIN COLD TOAST- methyl salicylate cream

Q.A. Laboratories

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.

Drug Facts

Active Ingredient Purpose

Methyl salicylate 31% topical analgesic

Menthol 11% topical analgesic

USES temporarily relieves minor body aches and pains of muscle and joints associated with: simple backache

arthritis sprains bruises strains

Warnings for external use only

Do not use i on wounds i on damaged skin
i with a heating pad i on a child under 12
years of age with arthritis-like conditions

Ask a doctor before use if you have
redness over the affected area.

When using this product i avoid contact
with eyes and mucous membranes i do
not bandage tightly

Stop use and ask doctor if ■ condition
worsens or symptoms persist for more than
7 days ■ symptoms clear up and occur within
a few days ■ excessive skin irritation occurs

Keep out of reach of children.

In case of accidental ingestion, get medical
help or contact a Poison Control Center right
away (1-800-222-1222)

Directions i use only as directed
i adults and children 12 years of age
or older: apply to af fected area not more
than 3 to 4 times daily i children under
12 years of age: ask a doctor

Other information

■ store between 20-25° C (68-77°F).

■ Protect from freezing

apply to affected area not more
than 3 to 4 times daily

Inactive ingredients
 DEIONIZED WATER, CETEARYL ALCOHOL,
 ISOPROPYL MYRISTATE, ISOCETYL STEARATE,
 POLYSORBATE 60, SODIUM POLYACRYLOYLDIMETHYL
 TAURATE, PHENOXYETHANOL,
 HYDROGENATED POLYDECENE, CHAMOMILLA
 RECUTITA (MATRICARIA) FLOWER EXTRACT,
 METHYL PARABEN, TRIDECETH-10,
 ROSMARINUS OFFICINALIS (ROSEMARY),
 LEAF EXTRACT, FRANKINCENSE EXTRACT,
 PROPYL PARABEN

Questions or comments:
 1-800-4NO-PAIN,
 toastproducts.com
 MFD FOR: Toast Products
 400 Sproul Street,
 Pittsburgh, PA 15136
 MFG IN USA

NDC 52099-8000

NATURAL PAIN RELIEF

Extra Strength
Pain Relieving Cream
 Targeted Relief for Muscle and Joint Pain
 DEEP PENETRATING
 START TO FEEL ON CONTACT
 Net Wt. 5oz. (141g)

Drug Facts

| Active Ingredient | Purpose |
|----------------------------|-------------------|
| Methyl salicylate 31%..... | Topical analgesic |
| Menthol 11%..... | Topical analgesic |

Uses temporarily relieves minor body aches and pains of muscles and joints associated with: simple backache ■ arthritis ■ sprains ■ bruises ■ strains

Warnings for external use only

Do not use ■ on wounds ■ on damaged skin ■ with a heating pad ■ on a child under 12 years of age with arthritis-like conditions

Ask a doctor before use if you have redness over the affected area.

When using this product ■ avoid contact with eyes and mucous membranes ■ do not bandage tightly

Stop use and ask doctor if ■ condition worsens or symptoms persist for more than 7 days ■ symptoms clear up and occur within a few days ■ excessive skin irritation occurs

Keep out of reach of children.
 In case of accidental ingestion, get medical help or contact a Poison Control Center right away (1-800-222-1222)

Directions ■ use only as directed

■ **adults and children 12 years of age or older:** apply to affected area not more than 3 to 4 times daily ■ **children under 12 years of age:** ask a doctor

Other Information

■ store between 20-25° C (68-77°F).
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Inactive Ingredients
 DEIONIZED WATER, CETEARYL ALCOHOL, ISOPROPYL MYRISTATE, ISOCETYL STEARATE, POLYSORBATE 60, SODIUM POLYACRYLOYLDIMETHYL TAURATE, PHENOXYETHANOL, HYDROGENATED POLYDECENE, CHAMOMILLA RECUTITA (MATRICARIA) FLOWER EXTRACT, METHYL PARABEN, TRIDECETH-10, ROSMARINUS OFFICINALIS (ROSEMARY), LEAF EXTRACT, FRANKINCENSE EXTRACT, PROPYL PARABEN

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FREEZIN COLD TOAST

methyl salicylate cream

Product Information

| | | | |
|-------------------------|----------------|--------------------|----------------|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:52099-8000 |
| Route of Administration | TOPICAL | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|--|-------------------|------------------|
| METHYL SALICYLATE (UNII: LAV5U5022Y) (SALICYLIC ACID - UNII:O414PZ4LPZ) | METHYL SALICYLATE | 31 g in 100 g |

MENTHOL, UNSPECIFIED FORM (UNII: L7T10EIP3A) (MENTHOL - UNII:L7T10EIP3A)

MENTHOL, UNSPECIFIED FORM

11 g
in 100 g

Inactive Ingredients

| Ingredient Name | Strength |
|--|----------|
| WATER (UNII: 059QF0KO0R) | |
| CETOSTEARYL ALCOHOL (UNII: 2DMT128M1S) | |
| ISOPROPYL MYRISTATE (UNII: 0RE8K4LNJS) | |
| ISOCETYL STEARATE (UNII: 3RJ7186O9W) | |
| POLYSORBATE 60 (UNII: CAL22UVI4M) | |
| PHENOXYETHANOL (UNII: HIE492ZZ3T) | |
| HYDROGENATED POLYDECENE TYPE I (UNII: U333RI6EB7) | |
| MATRICARIA CHAMOMILLA WHOLE (UNII: G0R4UBI2ZZ) | |
| METHYLPARABEN (UNII: A2I8C7HI9T) | |
| TRIDECETH-10 (UNII: G624N6MSBA) | |
| FRANKINCENSE (UNII: R9XLF1R1WM) | |
| ROSEMARY (UNII: IJ67X351P9) | |
| PROPYLPARABEN (UNII: Z8IX2SC1OH) | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|--|----------------------|--------------------|
| 1 | NDC:52099-8000-1 | 141 g in 1 TUBE; Type 0: Not a Combination Product | 06/12/2012 | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|-------------------------|--|----------------------|--------------------|
| OTC monograph not final | part348 | 06/12/2012 | |

Labeler - Q.A. Laboratories (065361149)

Registrant - Q.A. Laboratories (065361149)

Establishment

| Name | Address | ID/FEI | Business Operations |
|-------------------|---------|-----------|-------------------------|
| Q.A. Laboratories | | 065361149 | manufacture(52099-8000) |

Revised: 1/2022

Q.A. Laboratories