FAMILY WELLNESS ICE BLUE- menthol gel FAMILY DOLLAR SERVICES 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.

Active ingredient

Menthol 2 percentage

Purpose

External pain reliever

Uses

Temporary relief of minor pains of muscle and joints associated with simple back ache arthritis sprains, strains or bruises

Warnings

Do not use internally, with heating pads or devices, on wounds or damaged skin.

For external use only.

Ask a doctor before use if you have sensitive skin.

When using this product

Use only as directed do not bandage tightly avoid contact with eyes and mucus membranes

Stop use and ask a doctor if

condition worsens

symptoms persist for more than 7 days or clear up and occur again within a few days skin irritation develops

If you are pregnant or nursing a baby,

concult a physician before use.

KEEP OUT OF REACH OF CHILDREN.

DO NOT APPLY TO CHILDREN UNDER 2 YEARS OF AGE.

In case of accidental ingestion, get medical help or contact a Posion Control Center immediately.

Directions

Adult and children 2 years of age and older:

Clean skin thoroughly. Apply liberally to affected area not more than 3-4 times daily. No protective cover needed.

May be used with ice packs.

May be used with wet or dry bandages, but wrap loosely.

Children under 2 years of age, consult a doctor.

Other information

store between 59 - 86 Fahrenheit (15 - 30 degrees Celsius) keep tightly closed do not use, pour, spill or store near heat or open flame.

Inactive ingredients

Blue 1, Camphor, Carbomer, Isopropyl Alcohol, Methylchoroisothiazolinone, Methylisothiazolinone, Sodium Hydroxide, Water



FAMILY WELLNESS ICE BLUE

menthol gel

| Product Information | | | | |
|-------------------------|----------------|--------------------|---------------|--|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:55319-990 | |
| Route of Administration | TOPICAL | | | |

| ı | Active Ingredient/Active Moiety | | | | |
|---|--|-------------------|--------------|--|--|
| l | Ingredient Name | Basis of Strength | Strength | | |
| ı | MENTHOL (UNII: L7T10EIP3A) (MENTHOL - UNII:L7T10EIP3A) | MENTHOL | 2 g in 100 g | | |

| Inactive Ingredients | | |
|---|----------|--|
| Ingredient Name | Strength | |
| METHYLISO THIAZO LINO NE (UNII: 229 D0 E1QFA) | | |
| WATER (UNII: 059QF0KO0R) | | |
| CAMPHOR (SYNTHETIC) (UNII: 5TJD82A1ET) | | |

| ISOPROPYL ALCOHOL (UNII: ND2M416302) | |
|--|--|
| METHYLCHLOROISOTHIAZOLINONE (UNII: DEL7T5QRPN) | |
| SODIUM HYDRO XIDE (UNII: 55X04QC32I) | |
| CARBOMER 934 (UNII: Z135WT9208) | |
| FD&C BLUE NO. 1 (UNII: H3R47K3TBD) | |

| ı | Packaging | | | |
|---|--------------------|--|-----------------------------|---------------------------|
| ı | # Item Code | Package Description | Marketing Start Date | Marketing End Date |
| ı | 1 NDC:55319-990-01 | 226 g in 1 BOTTLE; Type 0: Not a Combination Product | 06/01/2020 | |

| Marketing Information | | | | |
|-------------------------|--|----------------------|--------------------|--|
| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date | |
| OTC monograph not final | part348 | 06/01/2020 | | |
| | | | | |

Labeler - FAMILY DOLLAR SERVICES INC (024472631)

Registrant - Family Dollar Services Inc (024472631)

| Establishment | | | | |
|---|---------|-----------|----------------------------|--|
| Name | Address | ID/FEI | Business Operations | |
| Ningbo Liyuan Daily Chemical Products Co., Ltd. | | 530766098 | manufacture(55319-990) | |

Revised: 6/2020 FAMILY DOLLAR SERVICES INC