

COLD ZONE PAIN RELIEVING GEL- DG HEALTH- menthol gel
Yash Pharmaceuticals

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.

Cold Zone Pain Relieving Gel- DG Health

Active Ingredients

Menthol USP 4%

Purpose

Cooling Pain Relief

Uses

Temporary relief from minor aches and pains of sore muscles and joints associated with: - arthritis - backache - strains - sprains

Warnings:

For external use only

Flammable:

Keep away from excessive heat or open flame.

Ask a doctor before use if you have:

sensitive skin

When using this product:

- Avoid contact with the eyes or mucous membranes
- 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
- Wash hands after use with cool water
- Do not use with heating pad or device

Stop use and ask a doctor if:

Condition worsens, or if symptoms persist for more than 7 days, or clear up and recur

If pregnant or breast-feeding:

Ask a health professional before use

Keep out of reach of children:

If accidentally ingested, get medical help or contact a Poison Control Center immediately

Directions:

- **Adults and children 2 years of age and older:** Rub a thin film over affected areas not more than 4 times daily; massage not necessary
- **Children under 2 years of age:** Consult physician

Other Information:

Store in a cool dry place with lid closed tightly

Inactive Ingredients

Purified water, Glycerin, Isopropyl alcohol, Iso propyl myristate, Carbopol usp, Aloevera gel, Arnica montana flower extract, Articum lappa root (burdock) extract, Boswellia carterii resin extract, Calendula officinalis extract, Camellia sinensis leaf extract, Liex paraguariensis leaf extract, Melissa officinalis (lemon balm) leaf extract, Tocopheryl acetate, Triethanolamine, Colloidal silicon dioxide, Sorbic acid, Camphor, Brilliant blue, Tartrazin supra

Cold Zone Pain Relieving Gel- DG Health

| Cold Zone Pain Relief Gel | | | |
|---|---|--|---------------------------|
| Active Ingredient | | Menthol 4%.....Cooling Pain Relief | |
| BATCH NO. | MGL1801 | QUANTITY | 4x8x4x3x59.14ml= 96 TUBES |
| MFG.DATE | 04/2018 | SHIPPER NO. |of |
| EXP. DATE | 03/2020 | GROSS WT. | kg. |
| | | NET WT. | kg. |
| WARNING: KEEP OUT OF REACH OF CHILDREN AND PETS. FOR EXTERNAL USE ONLY. | | STORE IN A COOL DRY PLACE | |
| CONFORMANCE WITH THE F.D & C ACT AND REGULATIONS THEREUNDER | | PROTECT FROM DIRECT SUNLIGHT/MOISTURE/FREEZING | |
| MANUFACTURED BY: YASH PHARMACEUTICALS KHASRA NO. 19-M, VILLAGE :RAIPUR PARGANA: BHAGWANPUR,DIST: HARIDWAR ROORKEE,UTTARAKHAND,INDIA 247667 | | | |
| Lic#UK/Drugs/39/UA/2016 | | | |
| LABELLER CODE | 71301 | | |
| SHIPPED TO: VELOCITY PHARMA LLC 226/B SHERWOOD AVE, FARMINGDALE , NY-11735 | | | |
| NDC No | 76168-401-41 | | |
| Barcode No. |  3 76168 40141 7 | | |

THIS SIDE UP

COLD ZONE PAIN RELIEVING GEL- DG HEALTH

menthol gel

Product Information

| | | | |
|--------------------------------|----------------|---------------------------|----------------|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:7130 1-007 |
| Route of Administration | TOPICAL | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|---|-------------------|---------------|
| MENTHOL (UNII:L7T10EIP3A) (MENTHOL - UNII:L7T10EIP3A) | MENTHOL | 40 mg in 1 mL |

Inactive Ingredients

| Ingredient Name | Strength |
|---|----------|
| CAMPHOR (NATURAL) (UNII: N20HL7Q941) | |
| BRILLIANT BLUE G (UNII: MIZRX790SI) | |
| PETROLATUM (UNII: 4T6H12BN9U) | |
| CARBOXYPOLYMETHYLENE (UNII: 0A5MM307FC) | |
| ALOE VERA LEAF (UNII: ZY81Z83H0X) | |
| ARNICA MONTANA FLOWER (UNII: OZ0E5Y15PZ) | |
| ARCTIUM LAPPA WHOLE (UNII: 73070DU1LA) | |
| CALENDULA OFFICINALIS FLOWER (UNII: P0M7O4Y7YD) | |
| FRANKINCENSE (UNII: R9XLF1R1WM) | |
| GREEN TEA LEAF (UNII: W2ZU1RY8B0) | |
| ILEX PARAGUARIENSIS LEAF (UNII: 1Q953B4O4F) | |
| MELISSA OFFICINALIS LEAF (UNII: 50D2ZE9219) | |
| ISOPROPYL ALCOHOL (UNII: ND2M416302) | |
| ISOPROPYL MYRISTATE (UNII: 0RE8K4LNJS) | |
| .ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0) | |
| SILICON DIOXIDE (UNII: ETJ7Z6XBU4) | |
| TROLAMINE (UNII: 9O3K93S3TK) | |
| SORBIC ACID (UNII: X045WJ989B) | |
| WATER (UNII: 059QF0KO0R) | |
| FD&C BLUE NO. 1 (UNII: HBR47K3TBD) | |
| FD&C YELLOW NO. 5 (UNII: I753WB2F1M) | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|---|----------------------|--------------------|
| 1 | NDC:71301-007-01 | 96 in 1 PACKAGE | 04/12/2018 | |
| 1 | | 59.14 mL in 1 TUBE; 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 | 01/22/2018 | |

Labeler - Yash Pharmaceuticals (871409551)

Revised: 4/2018

Yash Pharmaceuticals