

**COLD ZONE PAIN RELIEVING GEL- DG HEALTH- menthol gel**  
**Velocity Pharma LLC**

*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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**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 RELIEVING GEL- DG HEALTH

menthol gel

### Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:76 168-451
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: H3R47K3TBD)	
FD&C YELLOW NO. 5 (UNII: I753WB2F1M)	

**Packaging**

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:76168-451-41	59.14 mL in 1 BOTTLE; Type 0: Not a Combination Product	01/22/2018	

**Marketing Information**

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part348	01/22/2018	

**Labeler** - Velocity Pharma LLC (962198409)

Revised: 5/2018

Velocity Pharma LLC