

COLD ZONE PAIN RELIEVING GEL- RITE AID- 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.

Cold Zone Pain Relieving Gel- Rite Aid

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.

Questions or Comments - Call 1-855-314-1850

Inactive Ingredients

Purified water, Glycerin, Isopropyl alcohol, Iso propyl myristate, Carbopol usp, Aloe vera gel, Arnica montana flower extract, Articum lappa root (burdock) extract, Boswellia carterii resin extract, Calendula officinalis extract, Camellia sinensis leaf extract, camphor⁹³⁴, colloidal silicon dioxide, FD&C blue no. 1, FD&C yellow no. 5, glycerin, liex paraguariensis leaf extract, Isopropyl alcohol, Isopropyl myristate, Melissa officinalis (lemon balm) leaf extract, Tocopheryl acetate, Triethanolamine, Sorbic acid.

Cold Zone Pain Relieving Gel- Rite Aid



*Compare to the active ingredient of Biofreeze® Gel

pain care cold therapy gel

4% menthol

for arthritis, back pain, sore muscles and joints

soothing menthol vanishing scent paraben-free

3 FL OZ (88.72 mL)



372514

Drug Facts

Active ingredient: Menthol 4% **Purpose:** Cooling Pain Relief

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Inactive ingredients:

aloe vera gel, arnica montana flower extract, articum lappa root (burdock) extract, boswellia carterii resin extract, calendula officinalis extract, camellia sinensis (green tea) leaf extract, camphor, carbomer 934, colloidal silicon dioxide, FD&C blue no.1, FD&C yellow no.5, glycerin, ilex paraguariensis leaf extract, isopropyl alcohol, isopropyl myristate, melissa officinalis (lemon balm) leaf extract, purified water, sorbic acid, tocopheryl acetate, triethanolamine

Questions or comments 1-855-314-1850

GUJ/DRUGS/G/25/2169

Keep cap tightly closed between uses. Does not contain NSAIDs, Ibuprofen, Aspirin or Salicylate

DISTRIBUTED BY: RITE AID, 30 HUNTER LANE, CAMP HILL, PA 17011
MADE IN INDIA
*This product is not manufactured by or distributed by Performance Health, LLC, owner of trademark of BIOFREEZE® GEL

Compare to the active ingredient of
Biofreeze® Gel*

COLD THERAPY GEL

4% MENTHOL

for arthritis, back pain,
sore muscles & joints

soothing menthol
vanishing scent
paraben-free



3 FL OZ (88.72 mL)

Keep cap tightly closed between uses. Does not contain NSAIDs, Ibuprofen, Aspirin or Salicylate



Drug Facts

Active ingredient:	Purpose
Menthol 4%	Cooling Pain Relief

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

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Questions or comments 1-855-314-1850

Neutral Code: HP/Drugs/MNB/16/931

DISTRIBUTED BY: RITE AID, 30 HUNTER LANE, CAMP HILL, PA 17011 www.riteaid.com **MADE IN INDIA**
SATISFACTION GUARANTEE: If you're not satisfied, we'll happily refund your money.
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COLD ZONE PAIN RELIEVING GEL- RITE AID

menthol gel

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:76168-314
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: M1ZR790SI)				
PETROLATUM (UNII: 4T6H12BN9U)				
CARBOXYPOLYMETHYLENE (UNII: 0A5MM307FC)				
ALOE VERA LEAF (UNII: ZY81Z83H0X)				
ARNICA MONTANA FLOWER (UNII: OZ0E5Y15PZ)				
ARCTIUM LAPP A 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:76168-314-48	88.72 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)