

**DG HEALTH COLD ZONE PAIN RELIEVING TOPICAL ANALGESIC- menthol,
unspecified form gel
Dolgenercorp Inc**

**DG Health Cold Zone Pain Relieving Gel
Topical Analgesic**

Drug Facts

Active ingredient

Menthol 4%

Purpose

Topical analgesic

Uses

for the temporary relief of minor aches and pains of muscles and joints associated with simple backache, arthritis, strains, bruises, and sprains

Warnings

For external use only

When using this product

- avoid contact with eyes
- do not apply to wounds or damaged skin
- do not bandage tightly
- do not use with heating pads or other heating devices

Stop use and consult a doctor if condition worsens, or if symptoms persist for more than 7 days or clear up and occur again within a few days.

Flammable

- keep away from fire or flame

If pregnant or breast-feeding, ask a health professional before use.

Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center (1-800-222-1222) immediately.

Directions

adults and children 6 years of age and older apply to affected area not more than 3-4 times daily. Children under 6 years of age: *Do Not Use*.

Inactive ingredients

aloe barbadensis leaf juice, arnica montana flower extract, blue 1, boswellia serrata resin extract, calendula officinalis flower extract, camellia sinensis leaf extract, camphor, carbomer, glycerin, isopropyl alcohol, isopropyl myristate, sodium hydroxide, tocopheryl acetate, water, yellow 5.

Questions or comments?

1-888-309-9030

DISTRIBUTED BY
OLD EAST MAIN CO.
100 MISSION RIDGE
GOODLETTSVILLE, TN 37072

PRINCIPAL DISPLAY PANEL - 59 mL Tube Label

DG™ |health

Compare to
active
ingredient
of BIOFREEZE®
GEL*

Cold Zone
Pain Relieving
Gel

Topical Relief
Menthol 4% Topical Analgesic

- For arthritis, backache, muscle pain and joint pain
- Soothing Menthol
- Paraben free

2 FL OZ (59 mL)

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*This product is not manufactured or distributed by Hygenic Inc. Property Holding Co., owner of the registered trademark BIOFREEZE®.

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MADE IN CANADA 02-215

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DG HEALTH COLD ZONE PAIN RELIEVING TOPICAL ANALGESIC

menthol, unspecified form gel

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:55910-884
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

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

Inactive Ingredients

Ingredient Name	Strength
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Aloe Vera Leaf (UNII: ZY81Z83H0X)
Arnica Montana Flower (UNII: OZ0E5Y15PZ)
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)
INDIAN FRANKINCENSE (UNII: 4PW41QCO2M)
CALENDULA OFFICINALIS FLOWER (UNII: P0M7O4Y7YD)
GREEN TEA LEAF (UNII: W2ZU1RY8B0)
CAMPHOR (SYNTHETIC) (UNII: 5TJD82A1ET)
CARBOMER HOMOPOLYMER, UNSPECIFIED TYPE (UNII: 0A5MM307FC)
Glycerin (UNII: PDC6A3C0OX)
Isopropyl Alcohol (UNII: ND2M416302)
Isopropyl Myristate (UNII: 0RE8K4LNJS)
Sodium Hydroxide (UNII: 55X04QC32I)
.ALPHA.-TOCOPHEROL ACETATE, DL- (UNII: WR1WPI7EW8)
Water (UNII: 059QF0KO0R)
FD&C YELLOW NO. 5 (UNII: I753WB2F1M)

Product Characteristics

Color	green	Score	
Shape		Size	
Flavor		Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:55910-884-01	59 mL in 1 TUBE; Type 0: Not a Combination Product	03/05/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M017	03/05/2020	

Labeler - Dolgencorp Inc (068331990)

Registrant - Garcoa, Inc. (036464697)

Establishment

Name	Address	ID/FEI	Business Operations
SV Labs Toronto Corporation		203917476	manufacture(55910-884)