DG HEALTH COLD ZONE PAIN RELIEVING TOPICAL ANALGESIC- menthol, unspecified form gel Dolgencorp 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.

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 serrtata 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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MADE IN CANADA 02-215

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



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 MENTHOL, UNSPECIFIED FORM UNSPECIFIED FORM in 1 mL

Inactive Ingredients

Ingredient Name Strength

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: 1753WB2F1M)

Product Characteristics					
Color	GREEN	Score			
Shape		Size			
Flavor		Imprint Code			
Contains					

ı	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 NOT FINAL	part348	03/05/2020			

Labeler - Dolgencorp Inc (068331990)

Registrant - Garcoa, Inc. (036464697)

Establishment					
Name	Address	ID/FEI	Business Operations		
Sigan Industries INC.		255106239	MANUFACTURE(55910-884)		

Revised: 1/2022 Dolgencorp Inc