

FREEZE COOLING PAIN RELIEF- freeze cooling pain relief gel
Shandong Vianor Healthy Science Co.,Ltd.

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.

69980-102
FREEZE COOLING PAIN RELIEF

Active Ingredient(s)

Menthol 4%

Purpose

/

Use

Adults and children 12 years and older: Apply a small amount to the affected area and massage gently, no more than 4 times per day. Wash hands with cool water after use.

Warnings

for external use only.

In case of Ingestion seek medical assistance.

If a rash appears, discontinue use.

Do not use

If you are allergic to any of the ingredients, on inflamed or broken skin around the eyes with other topical treatments under bandages or occlusive dressings on children under the age of 12

If you are allergic to any of the ingredients, on inflamed or broken skin around the eyes with other topical treatments under bandages or occlusive dressings on children under the age of 12

Consult your doctor or pharmacist before use if you are diabetic, pregnant or breastfeeding. have poor circulation, a skin condition or if symptoms persists.

Directions

Adults and children 12 years and older: Apply a small amount to the affected area and massage gently, no more than 4 times per day. Wash hands with cool water after use.

Other information

Inactive ingredients

Water, Alcohol Denat., Polysorbate-20, Glycerin, Propylene Glycol, Triethanolamine, Phenoxyethanol, Acrylates/ C10-30 Alkyl Acrylate Crosspolymer. Cinnamomum Camphora (Camphor) bark oil, Ethylhexylglycerin, limonene, Linalool, CI42090 (FD&C Blue 1), CL17200 (D&C Red 33).

Package Label - Principal Display Panel

69980-102-05 200ml

							操作	03
客户名称		产品名称	freeze	制图日期	2020.8.6	颜色	5色	
直径	50	净高	155	网线		备注		



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- under bandages or occlusive dressings
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Store in a cool dry place.
Keep out of sight and reach of children.
Once opened use within 12 months.

Active Ingredients: Menthol 4% per 200ml

Ingredients: Water, Alcohol Denat., Polysorbate-20, Glycerin, Propylene Glycol, Triethanolamine, Phenoxyethanol, Acrylates/C10-30 Alkyl Acrylate Crosspolymer, Cinnamomum Camphora (Camphor) bark oil, Ethylhexylglycerin, Limonene, Linalool, CI 42090 (FD&C Blue 1), CL17200 (D&C Red 33).

Manufactured For: Quality Health Innovations Ltd
1st Floor, 9 Exchange Place, I.F.S.C
Dublin 1, D01 X8h2, Ireland

Manufactured at No 35 Xiang Yu Street
Hedong District, Linyi, Shandong, 276000, China

freeze

Cooling pain relief

- Pain relieving gel
- For muscles and joints
- Cooling sensation



For temporary pain relief associated with sprains, strains, backache, arthritis and aching muscles and joints.

paingone
Fast, effective pain relief

烫银



69980-102-04 150ml

200ml e

08-2023 LOT 2020-08



PGF

							操作	03
客户名称		产品名称	freeze	制图日期	2020.8.6	颜色	5色	
直径	50	净高	155	网线		备注		



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69980-102-02 50ml

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直径	50	净高	155	网线		备注		



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69980-102-01 30ml

							操作	03
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直径	50	净高	155	网线		备注		



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69980-102-03 100ml

							操作	03
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直径	50	净高	155	网线		备注		



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69980-102-06 30ml

							操作	03
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直径	50	净高	155	网线		备注		



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69980-102-07 50ml

							操作	03
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直径	50	净高	155	网线		备注		



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freeze

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08-2023 **LOT** 2020-08 5 060035 705139

烫银



69980-102-08 100ml

							操作	03
客户名称		产品名称	freeze	制图日期	2020.8.6	颜色	5色	
直径	50	净高	155	网线		备注		



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69980-102-09 150ml

							操作	03
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直径	50	净高	155	网线		备注		



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Active Ingredients: Menthol 4% per 200ml

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freeze

Cooling pain relief

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烫银



69980-102-010 200ml

							操作	03
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直径	50	净高	155	网线		备注		



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freeze

Cooling pain relief

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Fast, effective pain relief

烫银



69980-102-011 227ml



freeze

Cooling pain relief

Drug Facts

Active Ingredient	Purpose
Menthol 4%	Cooling pain relief

Uses
Temporary pain relief associated with • sprains • strains • backache
• arthritis • aching muscles and joints.

Warnings
For external use only.

Flammable: Keep away from open flame or excessive heat.

Ask a doctor before use if you are:
• pregnant or breastfeeding • suffering from a skin condition

When using this product: • Avoid contact with the eyes or mucous membranes • Do not apply to wounds or inflamed or broken skin
• Cease use if a rash or irritation occurs • Do not use with other topical treatments • Do not use under bandages or occlusive dressings

Stop use and ask a doctor if: • Condition worsens • Symptoms persist for more than 7 days • Symptoms clear up and recur within a few days

Keep out of reach of children: • If swallowed, get medical help or contact a Poison Control Center immediately

Directions • Adults and children 2 years and older: Apply a small amount to the affected area and massage gently, no more than 4 times per day. Wash hands with cool water after use.
• **Children under 2 years of age:** Consult a doctor

Inactive Ingredients
Water, Alcohol Denat., Polysorbate-20, Glycerin, Propylene Glycol, Triethanolamine, Phenoxyethanol, Acrylates/C10-30 Alkyl Acrylate Crosspolymer, Cinnamomum Camphora (Camphor) bark oil, Ethylhexylglycerin, Limonene, Linalool, CI 42090 (FD&C Blue 1), CL17200 (D&C Red 33).

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Dublin 1, D01 X8h2, Ireland
+1 888-549-9799 www.paingone.com

Manufactured at No 35 Xiang Yu Street
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10-2022

LOT 2020-10

- Pain relieving gel
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- Cooling sensation



For temporary pain relief associated with sprains, strains, backache, arthritis and aching muscles and joints.

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8 OZ.
(227ml)

苏沪 freeze-50



FREEZE COOLING PAIN RELIEF

freeze cooling pain relief gel

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:69980-102
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
MENTHOL (UNII: L7T10EIP3A) (MENTHOL - UNII:L7T10EIP3A)	MENTHOL	4 g in 100 mL

Inactive Ingredients

Ingredient Name	Strength
CARBOMER INTERPOLYMER TYPE A (55000 CPS) (UNII: 59TL3WG5CO)	
LINALOOL, (+/-)- (UNII: D81QY6I88E)	
D&C RED NO. 33 (UNII: 9DBA0SBB0L)	
ALCOHOL (UNII: 3K9958V90M)	
POLYSORBATE 20 (UNII: 7T1F30V5YH)	
WATER (UNII: 059QF0KO0R)	
GLYCERIN (UNII: PDC6A3C0OX)	
CAMPHOR OIL (UNII: 75IZZ8Y727)	
LIMONENE, (+)- (UNII: GFD7C86Q1W)	
TROLAMINE (UNII: 9O3K93S3TK)	
ETHYLHEXYLGLYCERIN (UNII: 147D247K3P)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
FD&C BLUE NO. 1 (UNII: HBR47K3TBD)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:69980-102-01	30 mL in 1 BOTTLE; Type 0: Not a Combination Product	03/30/2020	
2	NDC:69980-102-02	50 mL in 1 BOTTLE; Type 0: Not a Combination Product	03/30/2020	
3	NDC:69980-102-03	100 mL in 1 BOTTLE; Type 0: Not a Combination Product	03/30/2020	
4	NDC:69980-102-04	150 mL in 1 BOTTLE; Type 0: Not a Combination Product	03/30/2020	
5	NDC:69980-102-05	200 mL in 1 BOTTLE; Type 0: Not a Combination Product	03/30/2020	
6	NDC:69980-102-06	30 mL in 1 BOTTLE; Type 0: Not a Combination Product	03/30/2020	
7	NDC:69980-102-07	50 mL in 1 BOTTLE; Type 0: Not a Combination Product	03/30/2020	
8	NDC:69980-102-08	100 mL in 1 BOTTLE; Type 0: Not a Combination Product	03/30/2020	
9	NDC:69980-102-09	150 mL in 1 BOTTLE; Type 0: Not a Combination Product	03/30/2020	
10	NDC:69980-102-10	200 mL in 1 BOTTLE; Type 0: Not a Combination Product	03/30/2020	
11	NDC:69980-102-11	227 mL in 1 BOTTLE; Type 0: Not a Combination Product	03/30/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part356	03/30/2020	

Establishment

Name	Address	ID/FEI	Business Operations
Shandong Vianor Healthy Science Co.,Ltd.		554532204	manufacture(69980-102)

Revised: 1/2021

Shandong Vianor Healthy Science Co.,Ltd.