## 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.

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69980-102 FREEZE COOLING PAIN RELIEF

### Active Ingredient(s)

Menthol 4%

### Purpose

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#### Use

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

### Warnings

for external use only. In cose of Ingestion seek medical assistance. If a rash appears, dis.continue use.

### Do not use

If you are allergle 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

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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 han 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, Cl42090 (FD&C Blue 1), CL17200 (D&C Red 33).

### Package Label - Principal Display Panel

69980-102-05 200ml

	7/-				24		52(		操 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
- · 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.

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, Cl 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

#### 200mle









freeze

Cooling pai

- Pain relieving gel
- For muscles and joints



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



	No.		407 646				M		操 03
客户	名称		产品名称	freeze	制图日期	2020.8.6	颜	色	5色
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#### 150mle









## freeze

## Cooling pain

- Pain relieving gel
- For muscles and joints



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



	775						M		操 03
客户	名称		产品名称	freeze	制图日期	2020.8.6	颜	色	5色
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#### 50mle





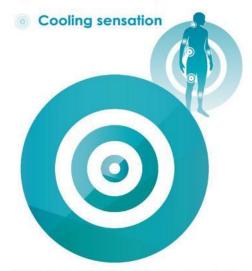
**2020-08 2020-08 2020-08** 



## freeze

## Cooling pain

- Pain relieving gel
- For muscles and joints



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



	No.		48				94		操 03
客户	名称		产品名称	freeze	制图日期	2020.8.6	颜	色	5色
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#### 30mle

**2020-08 2020-08 2020-08** 





# freeze

Cooling pain

For muscles and joints

Pain relieving gel

**Cooling sensation** 



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



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#### 100mle



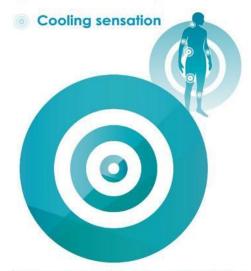




## freeze

## Cooling pain

- Pain relieving gel
- For muscles and joints



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



	ne.		45				20		操 03
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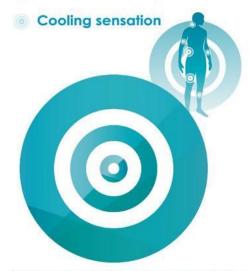




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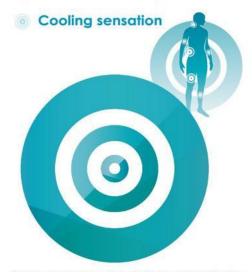
**2020-08 2020-08 2020-08** 



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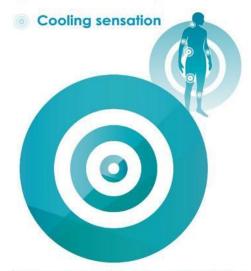
**2020-08 2020-08 2020-08** 



## freeze

## Cooling pain

- Pain relieving gel
- For muscles and joints



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	pre-		05				91		操 03
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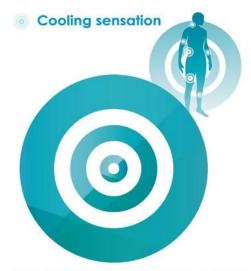




## freeze

Cooling pain

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





## **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

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Manufactured For: Quality Health Innovations Ltd 1st Floor, 9 Exchange Place, I.F.S.C Dublin 1, D01 X8h2, Ireland +1 888-549-9799 www.paingone.com

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# freeze

## Cooling pain relial

- Pain relieving gel
- For muscles and joints



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



8 OZ. (227ml)

苏沪 freeze-50



### FREEZE COOLING PAIN RELIEF

freeze cooling pain relief gel

<b>T</b>		T (	. •
Prod	uct	Infor	mation

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: 75IZZ8 Y727)				
LIMO NENE, (+)- (UNII: GFD7C86Q1W)				
TROLAMINE (UNII: 9O3K93S3TK)				
ETHYLHEXYLGLYCERIN (UNII: 147D247K3P)				
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)				
PHENO XYETHANO L (UNII: HIE492ZZ3T)				
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)				

Packaging						
#	Item Code	Package Description	<b>Marketing Start Date</b>	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.