

BIOFREEZE- menthol gel
Performance Health 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.

Biofreeze Pain Relieving Gel

Active Ingredients

Menthol USP 3.5%

Purpose

Cooling Pain Reliever

Uses

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

Warnings

For external use only.

Flammable

Keep away from excessive heat or open flame

Ask a doctor before use if you have:

sensitive skin

- 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 of symptoms persist for more than 7 days, or clear up and reoccur.

If pregnant or breastfeeding:

Ask a health professional before use.

Keep out of the 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

- carbomer, FD and C blue # 1, FD and C yellow # 5, glycerine, herbal extract (Ilex paraguariensis), isopropyl alcohol USP, methylparaben, natural camphor USP (for scent), propylene glycol, silicon dioxide, triethanolamine, purified water U

Questions or Comments?

1-330-633-8460

BIOFREEZE - menthol gel (59316-101-10)



NDC 59316-101-10

Drug Facts	
Active Ingredients	Purpose
Menthol USP 3.5%	Cooling Pain Reliever
Uses: Temporary relief from minor aches and pains of sore muscles & 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 reoccur.	
If pregnant or breastfeeding: 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	
Inactive Ingredients: carborer, FD&C blue #1, FD&C yellow #5, glycoline, herbal extract (Ilex paraguariensis), isopropyl alcohol USP, methylparaben, natural camphor USP (for scent), propylene glycol, silicon dioxide, triethanolamine, purified water USP	

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BUSAGRA 001 • REV 5
Questions or Comments? 1-800-246-3733



No Animal Testing



Manufactured
in the U.S.A.

BIOFREEZE - menthol gel (59316-101-11)

**PENETRATING, LONG LASTING PAIN RELIEF FROM:
ARTRITIS • SORE MUSCLES & JOINTS • BACK PAIN**



1 fl oz / 30 mL

**WITH SOOTHING MENTHOL
Cryotherapy - The Cold Method®**



Formulated For Authorized Distribution Through
Hands-On Health Professionals For
The Patients, Clients, & Athletes Under Their Care

Drug Facts	
Active Ingredients	Purpose
Menthol USP 3.5%	Cooling Pain Reliever
Uses: Temporary relief from minor aches and pains of sore muscles & 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	
Inactive Ingredients: carbomer, FD&C blue #1, FD&C yellow #5, glycerine, herbal extract (<i>Ilex paraguariensis</i>), isopropyl alcohol USP, methylparaben, natural camphor USP (for scent), propylene glycol, silicon dioxide, triethanolamine, purified water USP	
Questions or Comments? 800-246-3733	

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REV 0 • NDC 59316-101-11

Manufactured in the U.S.A. No Animal Testing

BIOFREEZE - menthol gel (59316-101-13)

Formulated For Authorized Distribution Through Hands-On Health Professionals For The Patients, Clients & Athletes Under Their Care

Drug Facts

Active Ingredients	Purpose
Menthol USP 3.5%	Cooling Pain Reliever

Uses: Temporary relief from minor aches and pains of sore muscles & 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 reoccur

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:

Roll on to the 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

Inactive Ingredients: carbomer, FD&C blue #1, FD&C yellow #5, glycerine, herbal extract (Ilex paraguariensis), isopropyl alcohol USP, methylparaben, natural camphor USP (for scent), propylene glycol, silicon dioxide, triethanolamine, purified water USP

Questions or Comments? 1-800-246-3733

**PENETRATING, LONG LASTING PAIN RELIEF FROM:
 ARTHRITIS • SORE MUSCLES & JOINTS • BACK PAIN**

BIOFREEZE®
 PAIN RELIEVING Roll-On



2 fl oz / 59 mL

WITH SOOTHING MENTHOL
 Cryotherapy - The Cold Method®

**SHAKE WELL
 BEFORE
 EACH USE**



Apply by rolling in only one direction. Do not use a circular motion.



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 P06539
 REV 0



No Animal Testing

Manufactured in the U.S.A.

NDC 59316-101-13

BIOFREEZE - menthol gel (59316-101-12)

Sample Only - Not for Resale

PENETRATING, LONG LASTING PAIN RELIEF FROM:
ARTHRITIS • SORE MUSCLES & JOINTS • BACK PAIN



2 fl oz / 59 mL

WITH SOOTHING MENTHOL
Cryotherapy - The Cold Method®



Formulated For Authorized Distribution Through
Hands-On Health Professionals For
The Patients, Clients, & Athletes Under Their Care

Drug Facts	
Active Ingredients	Purpose
Menthol USP 3.5%	Cooling Pain Reliever
Uses: Temporary relief from minor aches and pains of sore muscles & 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	
Inactive Ingredients: carbomer, FD&C blue #1, FD&C yellow #5, glycerine, herbal extract (Ilex paraguensis), isopropyl alcohol USP, methylparaben, natural camphor USP (for scent), propylene glycol, silicon dioxide, triethanolamine, purified water USP	
Questions or Comments? 800-246-3733	

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Manufactured in the U.S.A. No Animal Testing

BIOFREEZE - menthol gel (59316-101-15)

Formulated For Authorized Distribution Through Hands-On Health Professionals For The Patients, Clients & Athletes Under Their Care

Drug Facts	
Active Ingredients	Purpose
Menthol USP 3.5%	Cooling Pain Reliever
Uses: Temporary relief from minor aches and pains of sore muscles & 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 reoccur	
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: Roll on to the 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	
Inactive Ingredients: carbomer, FD&C blue #1, FD&C yellow #5, glycerine, herbal extract (Ilex paraguariensis), isopropyl alcohol USP, methylparaben, natural camphor USP (for scent), propylene glycol, silicon dioxide, triethanolamine, purified water USP	
Questions or Comments? 1-800-246-3733	

**PENETRATING, LONG LASTING PAIN RELIEF FROM:
ARTHRITIS • SORE MUSCLES & JOINTS • BACK PAIN**



3 fl oz / 89 mL

WITH SOOTHING MENTHOL
Cryotherapy - The Cold Method®

SHAKE WELL BEFORE EACH USE



Apply by rolling in only one direction. Do not use a circular motion.



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REV 7



No Animal Testing
Manufactured in the U.S.A.
NDC 59316-101-15

BIOFREEZE - menthol gel (59316-101-20)

PENETRATING, LONG LASTING PAIN RELIEF FROM:
 ARTHRITIS • SORE MUSCLES & JOINTS • BACK PAIN



4 fl oz / 118 mL

WITH SOOTHING MENTHOL
 Cryotherapy - The Cold Method®



Formulated For Authorized Distribution Through
 Hands-On Health Professionals For
 The Patients, Clients, & Athletes Under Their Care

Drug Facts	
Active Ingredients	Purpose
Menthol USP 3.5%	Cooling Pain Reliever
Uses	
Temporary relief from minor aches and pains of sore muscles & 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	
Inactive Ingredients: carbomer, FD&C blue #1, FD&C yellow #5, glycerine, herbal extract (Hex pasaguriensis), isopropyl alcohol USP, methylparaben, natural camphor USP (for scent), propylene glycol, silicon dioxide, triethanolamine, purified water USP	
Questions or Comments? 1-800-246-3733	

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Manufactured in the U.S.A. No Animal Testing

BIOFREEZE - menthol gel (59316-101-30)

Penetrating, long lasting pain relief from:
Arthritis • sore muscles & joints • back pain

BIOFREEZE[®]

PAIN RELIEVING Gel



16 fl oz / 473 mL

WITH SOOTHING MENTHOL

Cryotherapy - The Cold Method[®]

See

Formulated For Authorized Distribution Through Hands-On Health Professionals For The Patients, Clients & Athletes Under Their Care.

Drug Facts	
Active Ingredients Menthol USP 3.5%.....	Purpose Cooling Pain Reliever
Uses Temporary relief from minor aches and pains of sore muscles & 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	
Inactive Ingredients: carbomer, FD&C blue #1, FD&C yellow #5, glycerine, herbal extract (Ilex paraguariensis), isopropyl alcohol USP, methylparaben, natural camphor USP (for scent), propylene glycol, silicon dioxide, triethanolamine, purified water USP	
Questions or Comments? 800-246-3733	

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NDC 58316-101-30

Manufactured in the U.S.A.
No Animal Testing



BIOFREEZE - menthol gel (59316-101-50)

9.375" Seam to Seam

Penetrating, long lasting pain relief from:
Arthritis • sore muscles & joints • back pain

BIOFREEZE[®]

PAIN RELIEVING Gel

WITH SOOTHING MENTHOL

Cryotherapy - The Cold Method[®]

128 fl oz / 3785 mL

Handle 5

Formulated For Authorized Distribution Through Hands-On Health Professionals For The Patients, Clients, & Athletes Under Their Care

Drug Facts		
Active Ingredients Menthol USP 3.5%.....	Purpose Cooling Pain Reliever	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.
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		
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		
Inactive Ingredients: carbomer, FD&C blue #1, FD&C yellow #5, glycerine, herbal extract (Ilex paraguariensis), isopropyl alcohol USP, methylparaben, natural camphor USP (for scent), propylene glycol, silicon dioxide, triethanolamine, purified water USP		
Questions or Comments? 1-800-246-3733		



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NDC 58316-101-50

Manufactured in the U.S.A.

No Animal Testing



BIOFREEZE - menthol gel (59316-101-40)

PENETRATING, LONG LASTING PAIN RELIEF FROM:
 ARTHRITIS • SORE MUSCLES & JOINTS • BACK PAIN

BIOFREEZE[®]

gel

PAIN RELIEVING



32 fl oz / 946 mL

WITH SOOTHING MENTHOL
 Cryotherapy - The Cold Method[®]

Formulated For Authorized Distribution Through
 Hands-On Health Professionals For The Patients,
 Clients & Athletes Under Their Care.

Drug Facts	
Active Ingredients	Purpose
Menthol USP 3.5%	Cooling Pain Reliever
Uses	
Temporary relief from minor aches and pains of sore muscles & 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:	
<ul style="list-style-type: none"> • 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	
<ul style="list-style-type: none"> • 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	
Inactive Ingredients: carbomer, FD&C blue #1, FD&C yellow #5, glycerine, herbal extract (Ilex paraguariensis), isopropyl alcohol USP, methylparaben, natural camphor USP (for scent), propylene glycol, silicon dioxide, triethanolamine, purified water USP	
Questions or Comments? 800-246-3733	

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 NDC 59316-101-40

Manufactured in the U.S.A.
 No Animal Testing



BIOFREEZE

menthol gel

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:59316-101
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
MENTHOL (UNII: L7T10EIP3A) (MENTHOL - UNII:L7T10EIP3A)	MENTHOL	35 mg in 1 mL

Inactive Ingredients

Ingredient Name	Strength
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
FD&C YELLOW NO. 5 (UNII: I753WB2F1M)	
GLYCERIN (UNII: PDC6A3C0OX)	
ISOPROPYL ALCOHOL (UNII: ND2M416302)	

METHYL PARABEN (UNII: A2I8C7H9T)	
CAMPHOR (NATURAL) (UNII: N20HL7Q941)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
TROLAMINE (UNII: 9O3K93S3TK)	
WATER (UNII: 059QF0KO0R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:59316-101-10	5 mL in 1 PACKET; Type 0: Not a Combination Product	08/25/2016	
2	NDC:59316-101-15	89 mL in 1 BOTTLE, WITH APPLICATOR; Type 0: Not a Combination Product	08/25/2016	
3	NDC:59316-101-20	118 mL in 1 TUBE; Type 0: Not a Combination Product	08/25/2016	
4	NDC:59316-101-21	81 mL in 1 TUBE; Type 0: Not a Combination Product	08/25/2016	
5	NDC:59316-101-30	473 mL in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	08/25/2016	
6	NDC:59316-101-40	946 mL in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	08/25/2016	
7	NDC:59316-101-50	3785 mL in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	08/25/2016	
8	NDC:59316-101-25	118 mL in 1 TUBE, WITH APPLICATOR; Type 0: Not a Combination Product	08/25/2016	
9	NDC:59316-101-12	59 mL in 1 TUBE; Type 0: Not a Combination Product	08/25/2016	
10	NDC:59316-101-13	59 mL in 1 BOTTLE, WITH APPLICATOR; Type 0: Not a Combination Product	08/25/2016	
11	NDC:59316-101-11	30 mL in 1 BOTTLE; Type 0: Not a Combination Product	08/25/2016	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part348	08/25/2016	

Labeler - Performance Health LLC. (794324061)

Establishment

Name	Address	ID/FEI	Business Operations
Span Packaging Services LLC		557434805	manufacture(59316-101)

Establishment

Name	Address	ID/FEI	Business Operations
Cosmetic Essence,LLC		825646862	manufacture(59316-101)