

**BIOFREEZE PROFESSIONAL- menthol, unspecified form 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.*

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**Biofreeze Professional Gel**

***Drug Facts***

***Active Ingredients:***

Menthol USP 5%

***Purpose***

Cooling Pain Relief

***Uses:***

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

• Use only as directed • Avoid contact with 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 • Wash hands after use with cool water • Do not bandage or use with heating pad or device • Store in a cool dry place away from direct sunlight

**Stop use and ask a doctor If:**

You experience pain, swelling or blistering; condition worsens, or if symptoms persist for more than 7 days, or clear up and occur again within a few days

**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 four times daily; massage not necessary

- **Children under 2 years of age:** Consult physician

**Inactive Ingredients:**

Aloe Barbadosis Leaf Extract, Arctium Lappa Root (Burdock) Extract, Arnica Montana Flower Extract, Blue 1, Boswellia Carterii Resin Extract, Calendula Officinalis Extract, Camellia Sinensis Leaf Extract, Carbomer, Glycerin, Ilex Paraguariensis Leaf Extract, Isopropyl Alcohol, Isopropyl Myristate, Melissa Officinalis (Lemon Balm) Leaf Extract, Silica, Tocopheryl Acetate, Triethanolamine, Water, Yellow 5

**Questions or Comments:**

1-800-246-3733

**Package Labeling:59316-115-30**

**COLD THERAPY PAIN RELIEF FOR SORE MUSCLES, BACKACHES, SORE JOINTS AND ARTHRITIS**  
VANISHING SCENT • PARABEN-FREE

**CLINICALLY RECOMMENDED #1**

**BIOFREEZE<sup>®</sup> PROFESSIONAL**

**GEL**  
**LONGER LASTING\*<sup>†</sup>**  
**MENTHOL PAIN RELIEF**

16 FL. OZ. / 473 mL

**Drug Facts**

Active ingredients:	Purpose
Menthol USP 5%	Cooling Pain Relief

**Uses:**  
Temporary relief from minor aches and pains of sore muscles and joints associated with arthritis, backache, strains and sprains

**Warnings:**  
**For external use only**  
Ask a doctor before use if you have: Sensitive skin  
**Flammable:** Keep away from excessive heat or open flame

**When using this product:** • Use only as directed • Avoid contact with 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 • Wash hands after use with cool water • Do not bandage or use with heating pad or device • Store in a cool dry place away from direct sunlight

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**Inactive ingredients:** Aloe Barbadosis Leaf Extract, Arctium Lappa Root (Burdock) Extract, Arnica Montana Flower Extract, Blue 1, Boswellia Carterii Resin Extract, Calendula Officinalis Extract, Camellia Sinensis Leaf Extract, Carbomer, Glycerin, Ilex Paraguariensis Leaf Extract, Isopropyl Alcohol, Isopropyl Myristate, Melissa Officinalis (Lemon Balm) Leaf Extract, Silica, Tocopheryl Acetate, Triethanolamine, Water, Yellow 5

**Questions or comments:** 1-800-246-3733

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3 59316 11530 5

\*Trusted by pharmacists, physical therapists, chiropractors, massage therapists, podiatrists and athletic trainers. Biofreeze<sup>®</sup> Professional Gel is backed by 25 years of scientific research and clinician use and is specially formulated to last longer.  
- Lasts longer than regular Biofreeze<sup>®</sup>

Manufactured in the U.S.A.  
No Animal Testing  
Does not contain NSAIDs, Ibuprofen, Aspirin or Salicylate

LOT  
NDC 59316-115-30  
13425 P07888-R04

**Package Labeling:59316-115-20**



# BIOFREEZE<sup>®</sup> PROFESSIONAL

GEL

LONGER LASTING\*  
MENTHOL PAIN RELIEF

4 FL. OZ. / 118 mL

COLD THERAPY PAIN RELIEF FOR SORE MUSCLES,  
BACKACHES, SORE JOINTS AND ARTHRITIS  
VANISHING SCENT • PARABEN-FREE



3 59316 11520 6

Manufactured in the U.S.A.  
No Animal Testing  
Does not contain NSAIDs,  
Ibuprofen, Aspirin or Salicylates

+ Lasts longer than  
regular Biofreeze\*

<b>Drug Facts</b>	
<b>Active Ingredients:</b>	<b>Purpose</b>
Menthol USP 5%	Cooling Pain Relief
<b>Uses:</b>	
Temporary relief from minor aches and pains of sore muscles and joints associated with: • arthritis • backache • strains • sprains	
<b>Warnings:</b>	
<b>For external use only</b>	
Ask a doctor before use if you have: Sensitive skin	
Flammable: Keep away from excessive heat or open flame	
When using this product: • Use only as directed • Avoid contact with 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 • Wash hands after use with cool water • Do not bandage or use with heating pad or device • Store in a cool dry place away from direct sunlight	
Stop use and ask a doctor if: You experience pain, swelling or blistering; condition worsens, or if symptoms persist for more than 7 days, or clear up and occur again within a few days	
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	
<b>Directions:</b>	
• Adults and Children 2 years of age and older: Rub a thin film over affected areas not more 4 times daily; massage not necessary	
• Children under 2 years of age: Consult physician	
<b>Inactive Ingredients:</b> Aloe Barbadensis Leaf Extract, Arctium Lappa Root (Burdock) Extract, Arnica Montana Flower Extract, Blue 1, Boswellia Carterii Resin Extract, Calendula Officinalis Extract, Camellia Sinensis Leaf Extract, Carbomer, Glycerin, Ilex Paraguariensis Leaf Extract, Isopropyl Alcohol, Isopropyl Myristate, Melissa Officinalis (Lemon Balm) Leaf Extract, Silica, Tocopheryl Acetate, Triethanolamine, Water, Yellow 5	
<b>Questions or comments:</b> 1-800-246-3733	

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NDC 59316-115-20  
13407 P07875-R06

Package Labeling:59316-115-40

**COLD THERAPY PAIN RELIEF FOR SORE MUSCLES,  
BACKACHES, SORE JOINTS AND ARTHRITIS**  
VANISHING SCENT • PARABEN-FREE



**Drug Facts**

Active ingredients:	Purpose
Menthol USP 5%	Cooling Pain Relief

**Uses:**  
Temporary relief from minor aches and pains of sore muscles and joints associated with arthritis, backache, strains and sprains

**Warnings:**  
**For external use only**  
Ask a doctor before use if you have: Sensitive skin  
Flammable: Keep away from excessive heat or open flame

**When using this product:** • Use only as directed • Avoid contact with 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 • Wash hands after use with cool water • Do not bandage or use with heating pad or device • Store in a cool dry place away from direct sunlight

**Stop use and ask a doctor if:** You experience pain, swelling or blistering; condition worsens, or if symptoms persist for more than 7 days, or clear up and occur again within a few days

**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 the affected areas not more than 4 times daily; massage not necessary  
• Children under 2 years of age: Consult physician

**Inactive ingredients:** Aloe Barbadensis Leaf Extract, Arctium Lappa Root (Burdock) Extract, Arnica Montana Flower Extract, Blue 1, Boswellia Carterii Resin Extract, Calendula Officinalis Extract, Camellia Sinensis Leaf Extract, Carbomer, Glycerin, Ilex Paraguariensis Leaf Extract, Isopropyl Alcohol, Isopropyl Myristate, Melissa Officinalis (Lemon Balm) Leaf Extract, Silica, Tocopheryl Acetate, Triethanolamine, Water, Yellow 5

**Questions or comments:** 1-800-246-3733

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- Lasts longer than regular Biofreeze®

Manufactured in the U.S.A.  
No Animal Testing  
Does not contain NSAIDs,  
Ibuprofen, Aspirin or Salicylate

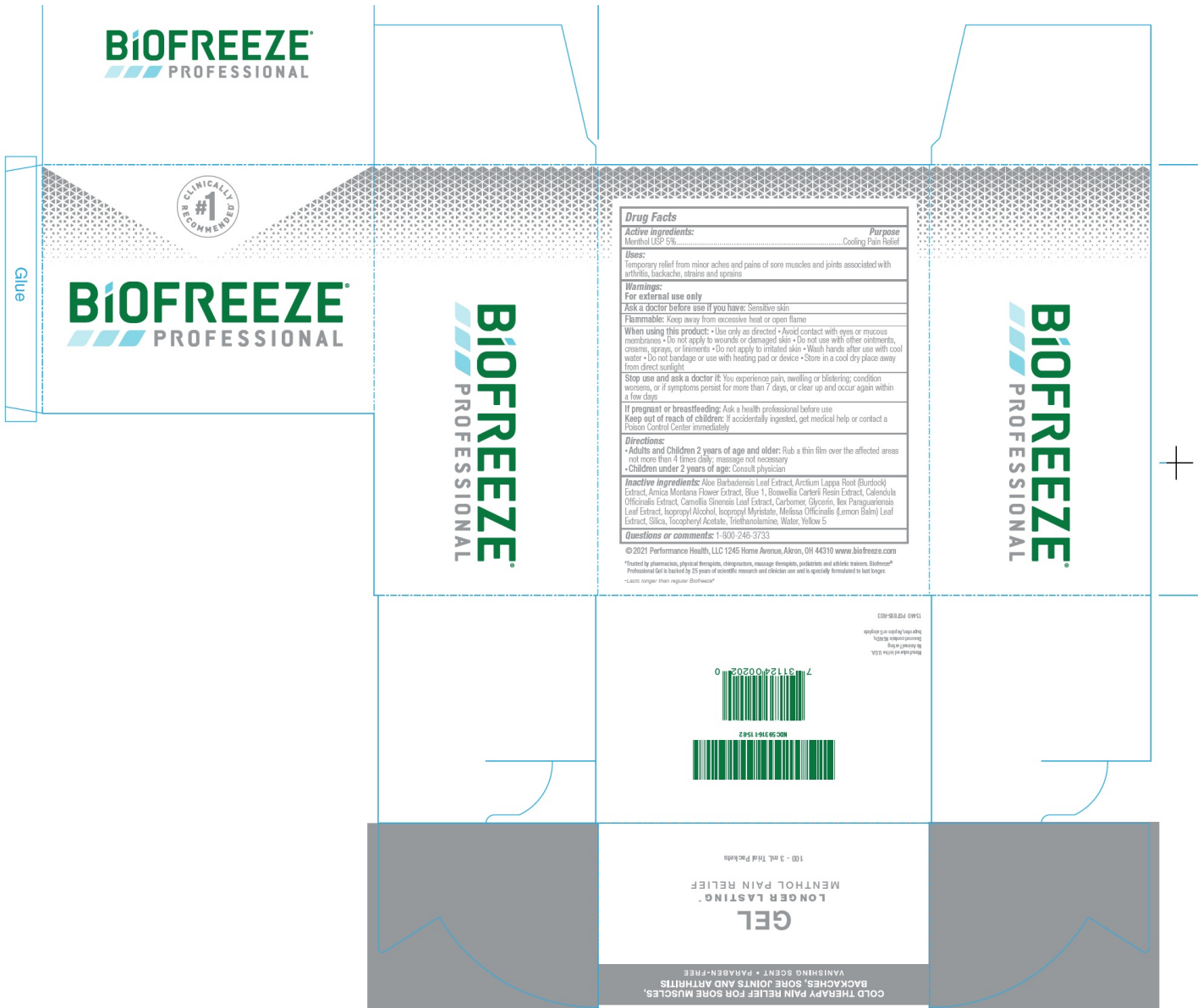
LOT  
NDC 59316-115-40  
13429 P07889-R04

**BIOFREEZE**  
PROFESSIONAL

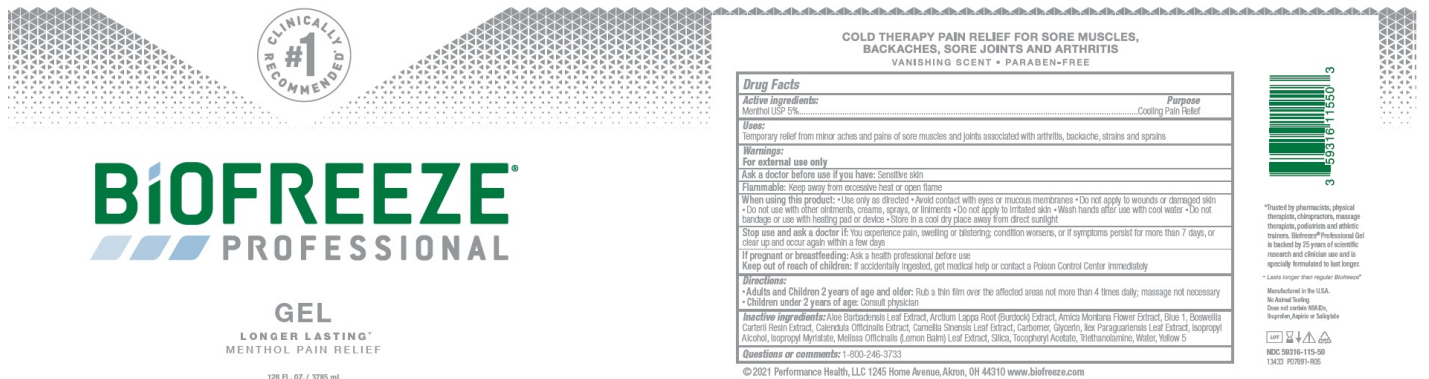
**GEL**  
LONGER LASTING\*  
MENTHOL PAIN RELIEF

32 FL. OZ. / 846 mL

**Package Labeling: 59316-115-11**



Package Labeling: 59316-115-50



Package Labeling: 59316-115-82



**COLD THERAPY PAIN RELIEF FOR SORE MUSCLES,  
BACKACHES, SORE JOINTS AND ARTHRITIS**  
VANISHING SCENT • PARABEN-FREE

**Drug Facts**

**Active ingredients:**  
Menthol USP 5%.....Cooling Pain Relief

**Purpose**

**Uses:** Temporary relief from minor aches and pains of sore muscles and joints associated with: • arthritis • backache • strains • sprains

**Warnings:**

**For external use only**

Ask a doctor before use if you have: Sensitive skin

**Flammable:** Keep away from excessive heat or open flame

**When using this product:** • Use only as directed • Avoid contact with 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 • Wash hands after use with cool water • Do not bandage or use with heating pad or device • Store in a cool dry place away from direct sunlight

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**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 four times daily; massage not necessary  
• **Children under 2 years of age:** Consult physician

**Inactive ingredients:** Aloe Barbadosis Leaf Extract, Arctium Lappa Root (Burdock) Extract, Arnica Montana Flower Extract, Blue 1, Boswellia Carterii Resin Extract, Calendula Officinalis Extract, Camellia Sinensis Leaf Extract, Carbomer, Glycerin, Ilex Paraguariensis Leaf Extract, Isopropyl Alcohol, Isopropyl Myristate, Melissa Officinalis (Lemon Balm) Leaf Extract, Silica, Tocopheryl Acetate, Triethanolamine, Water, Yellow 5

**Questions or comments:** 1-800-246-3733

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LOT     NDC 59316-115-11  
13435 P07892-R05

No Animal Testing • Does not contain NSAIDs, Ibuprofen, Aspirin or Salicylate • Lasts longer than regular Biofreeze®



**BIOFREEZE**  
PROFESSIONAL

**GEL**

LONGER LASTING\* MENTHOL PAIN RELIEF

3 mL

**BIOFREEZE PROFESSIONAL**

menthol, unspecified form gel

**Product Information**

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:59316-115
<b>Route of Administration</b>	TOPICAL		

**Active Ingredient/Active Moiety**

Ingredient Name	Basis of Strength	Strength
MENTHOL, UNSPECIFIED FORM (UNII: L7T10EIP3A) (MENTHOL - UNII:L7T10EIP3A)	MENTHOL, UNSPECIFIED FORM	50 mg in 1 mL

**Inactive Ingredients**

Ingredient Name	Strength
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
ARCTIUM LAPPA ROOT (UNII: 597E9B3Z3)	
ARNICA MONTANA FLOWER (UNII: OZ0E5Y15PZ)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
FRANKINCENSE (UNII: R9XLF1R1WM)	

CALENDULA OFFICINALIS FLOWER (UNII: P0M7O4Y7YD)	
GREEN TEA LEAF (UNII: W2ZU1RY8B0)	
CARBOXYPOLYMETHYLENE (UNII: 0A5MMB07FC)	
GLYCERIN (UNII: PDC6A3C0OX)	
ILEX PARAGUARIENSIS LEAF (UNII: 1Q953B4O4F)	
ISOPROPYL ALCOHOL (UNII: ND2M416302)	
ISOPROPYL MYRISTATE (UNII: 0RE8K4LNJS)	
MELISSA OFFICINALIS LEAF (UNII: 50D2ZE9219)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
TROLAMINE (UNII: 9O3K93S3TK)	
WATER (UNII: 059QF0KO0R)	
FD&C YELLOW NO. 5 (UNII: I753WB2F1M)	

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:59316-115-30	473 mL in 1 BOTTLE; Type 0: Not a Combination Product	06/03/2016	
2	NDC:59316-115-20	118 mL in 1 TUBE; Type 0: Not a Combination Product	06/03/2016	
3	NDC:59316-115-40	946 mL in 1 BOTTLE; Type 0: Not a Combination Product	06/03/2016	
4	NDC:59316-115-11	3 mL in 1 PACKET; Type 0: Not a Combination Product	06/03/2016	
5	NDC:59316-115-50	3785 mL in 1 BOTTLE; Type 0: Not a Combination Product	06/03/2016	
6	NDC:59316-115-82	100 in 1 CARTON	01/05/2019	
6		3 mL in 1 PACKET; Type 0: Not a Combination Product		

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part348	06/03/2016	

**Labeler** - Performance Health, LLC (794324061)