BIOFLEXOR- menthol gel
Health Care Laboratories 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.

Apply BioFlexor gel onto the affected area(s) up to 3 to 4 times daily as needed. Apply sufficient amount at bedtime for a restful sleep and in the morning to loosen stiff muscles and joints, and reduce pain. The therapeutic effects of BioFlexor will allow you to become more active and return to normal activities of daily living.

For External use only. Do not swallow. If Accidentally ingested, induce vomiting. Call a physician or poison control center immediately. If irritation develops, discontinue use of this product and consult a physician. Do not use on open sores, wounds, irritated or broken skin. Do not use with other creams, gels, ointments, topical medications, heating pads or other heat producing devices. Avoid contact with eyes or mucous membrane. Store in a cool dry place. Keep out of reach of children to avoid accidental poisoning. BioFlexor gel is contraindicated in patients with a known hypersensitivity to menthol. *For children under 2, pregnant or nursing mothers, consult a physician*.

0.25 oz (7.5 Gm) Jars NDC# 62391-001-10
2.25 oz (67.5 Gm) Jars NDC# 62391-001-02
4.5 oz (135 Gm) Jars NDC# 62391-001-04
32 oz (960 Gm) Jars NDC# 62391-001-30

TO PLACE ORDERS:
To place orders, please call customer service at:
1-800-909-9854
Or Fax orders to:
1-800-316-7853

Visit our website at:
www.bioflexor.com

Mfg. by HEALTH CARE LABS, INC.
P.O. Box 1734, Cleveland, TX 77328

Keep out of reach of children.

BioFlexor®
Deep Penetrating
Effective Pain Relief Gel

Description: BioFlexor® gel is an OTC topical analgesic preparation which delivers deep penetrating, effective pain relief. BioFlexor® is a unique product from several viewpoints. In developing BioFlexor®, our main focus was to formulate a potent topical analgesic agent that would minimize the need for oral narcotic analgesics. The result is an exceptional product that truly helps those individuals suffering from the pain associated with the spectrum of medical conditions from arthritis to muscle aches and pain, simple back aches, strains, bruises, and sprains. Menthol is the only listed active ingredient on the BioFlexor® label. The other all natural components work synergistically to produce the pain relieving activity. Another unique aspect of BioFlexor® relates to the immediate and long-lasting pain relief without the side effects of lingering scent (Methyl Salicylate rubs, ie. Ben Gay), burning sensation (Capsaicin ie. Zostrix, Theragesic, Icy-Hot), greasy residue (ie. Aspercreme, Ben-Gay), and dry skin (alcohol formulations, ie. Biofreeze). The BioFlexor® formulation contains no

alcohol, capsaicin, or methyl salicylate.

Mechanism of Action: The initial pain relief mechanism produced by the absorption of BioFlexor® generates a topical cooling effect. This is a result of vasoconstriction of peripheral vessels in the affected areas, yielding a decreased blood flow. This action causes a decrease in temperature of the skin and subcutaneous tissues. As penetration continues, an interruption of sympathetic nerve conduction occurs, producing a warm vasodilation. This in turn increases the blood flow to muscle tissues and to the surface of the skin, promoting the healing process and rendering analgesic properties. BioFlexor® gel is contraindicated in patients with a known hypersensitivity to menthol.

How Supplied:
2.25oz (67.5gm) Jars…..NDC# 62391-001-02
4.5oz (135gm) Jars …..…NDC# 62391-001-04

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Mfg. By: HEALTH CARE LABORATORIES, INC.
112 S. COLLEGE AVE. #100A
CLEVELAND, TX 77327
Store at controlled room temperature 15˚-30˚C (59˚-86˚F)
*Registered trademarks are the property of their respective owners.

DRUG FACTS
Active Ingredient Purpose
Menthol 3%, Topical Analgesic
Uses
Temporarily relieves the minor aches and pains of muscles and joints associated with:
•simple backache •arthritis •strains •bruises •sprains
Warnings
For external use only.
Do Not Use:
• on wounds or damaged skin
• with a heating pad
• on a child under 12 years of age with arthritis-like conditions
Ask a doctor before use if you have redness over the affected area.
When using this product:
• avoid contact with the eyes or mucous membranes
• do not bandage tightly
Stop use and ask a doctor if:
• condition worsens or symptoms persist for more than 7 days
• symptoms clear up and occur again within a few days
• excessive skin irritation occurs
Keep out of reach of children.
If swallowed, get medical help or contact the Poison Control Center right away.
Directions
Adults and children 12 years of age and older:
• apply to affected area not more than 3 to 4 times daily.
Children under 12 years of age:
• consult a doctor
Other Information
• Store at 20°-25°C (68°-77°)

• Lot No. and Expiration Date: See Container
Inactive Ingredients
Carbopolymer, Edetate Disodium Peacock Blue MX26,
Phenoxyethanol/Paraben Blend, Polysorbate 20, Potassium Sorbate,
Proprietary Blend, Purified Water, Sodium Hydroxide

Active Ingredient: Menthol 3%

Inactive Ingredients: Carbopol Polymer, Edetate Disodium, Peacock Blue MX26, Phenoxyethanol/Paraben Blend, Polysorbate 20, Potassium Sorbate, Proprietary Blend, Purified Water, Sodium Hydroxide

Description: BioFlexor® gel is an OTC topical analgesic preparation which delivers deep penetrating, effective pain relief. BioFlexor® is a unique product from several viewpoints. In developing BioFlexor®, our main focus was to formulate a potent topical analgesic agent that would minimize the need for oral narcotic analgesics. The result is an exceptional product that truly helps those individuals suffering from the pain associated with the spectrum of medical conditions from arthritis to muscle aches and pain, simple back aches, strains, bruises, and sprains. Menthol is the only listed active ingredient on the BioFlexor® label. The other all natural components work synergistically to produce the pain relieving activity. Another unique aspect of BioFlexor® relates to the immediate and long-lasting pain relief without the side effects of lingering scent (Methyl Salicylate rubs, ie. Ben Gay), burning sensation (Capsaicin ie. Zostrix, Theragesic, Icy-Hot), greasy residue (ie. Aspercreme, Ben-Gay), and dry skin (alcohol formulations, ie. Biofreeze).

The BioFlexor formulation contains no alcohol, capsaicin or methyl salicylate.

INDICATIONS: For the temporary relief of minor aches and pains of muscles and joints associated with simple backache, arthritis, strains, bruises, and sprains.

USAGE: Adults and children 12 years of age and older: Apply to affected area not more than 3 to 4 times daily. Children under 12 years of age, pregnant or nursing mothers: Consult a physician.

BioFlexor Jar

BIOFLEXOR
menthol gel

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:62391-001
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
MENTHOL (UNII: L7T10EIP3A) (MENTHOL - UNII:L7T10EIP3A)	MENTHOL	0.03 g in 1 g

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:62391-001-04	135 g in 1 JAR		
2	NDC:62391-001-02	67.5 g in 1 JAR		
3	NDC:62391-001-10	7.5 g in 1 JAR		
4	NDC:62391-001-30	960 g in 1 JAR		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part346	03/01/1998	

Labeler - Health Care Laboratories Inc. (088637298)

Establishment

Name	Address	ID/FEI	Business Operations
Health Care Laboratories Inc.		088637298	manufacture(62391-001)

Revised: 5/2014 Health Care Laboratories Inc.