

BIOFLEXOR 04- menthol gel
Health Care Laboratories Inc.

BioFlexor Deep Penetrating Gel

ACTIVE INGREDIENT

Active Ingredient: Purpose:

Menthol 3%Topical Analgesic

Purpose

Topical analgesic

INACTIVE INGREDIENTS

Inactive Ingredients: Aloe Vera Juice, Butyl Paraben, Camphor USP, Carbopol Polymer, Edetate Disodium, Ethyl Paraben, Eucalyptus Oil, Isobutyl Paraben, Methyl Paraben, Peacock Blue MX26, 2-Phenoxyethanol, Polysorbate 20, Potassium Sorbate, Propyl Paraben, Purified Water, Sodium Hydroxide, Yerba Mate, Yucca

WARNINGS SECTION

For external use only.

Keep out of reach of children. If swallowed, get medical help or contact the Poison Control Center right away.

Dosage and Administration

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

Uses

Temporarily relieves the minor aches and pains of muscles and joints associated with:

- simple backache
- arthritis
- strains
- bruises
- sprains

Store at 15°-30°C (59°-86°F)

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

PRINCIPAL DISPLAY PANEL

Bioflexor



BIOFLEXOR 04

menthol gel

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:62391-100
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
MENTHOL (UNII: L7T10EIP3A) (MENTHOL - UNII:L7T10EIP3A)	MENTHOL	3 g in 100 g

Inactive Ingredients

Ingredient Name	Strength
BUTYLPARABEN (UNII: 3QPI1U3FV8)	
CAMPHOR (SYNTHETIC) (UNII: 5TJD82A1ET)	
CARBOMER HOMOPOLYMER, UNSPECIFIED TYPE (UNII: 0A5MM307FC)	
EUCALYPTUS OIL (UNII: 2R04ONI662)	

PHENOXYETHANOL (UNII: HIE492ZZ3T)	
SODIUM HYDROXIDE (UNII: 55X04QC32I)	
ILEX PARAGUARIENSIS LEAF (UNII: 1Q953B4O4F)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	
ETHYLPARABEN (UNII: 14255EXE39)	
METHYLPARABEN (UNII: A2I8C7HI9T)	
PROPYLPARABEN (UNII: Z8IX2SC1OH)	
YUCCA SCHIDIGERA STEM (UNII: N59C6T6D72)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
ISOBUTYLPARABEN (UNII: 0QQJ25X58G)	
WATER (UNII: 059QF0KO0R)	
POTASSIUM SORBATE (UNII: 1VPU26JZZ4)	
POLYSORBATE 20 (UNII: 7T1F30V5YH)	

Product Characteristics

Color	turquoise	Score	
Shape		Size	
Flavor		Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:62391-100-04	135 g in 1 JAR; Type 0: Not a Combination Product	03/01/1998	
2	NDC:62391-100-02	67.5 g in 1 JAR; Type 0: Not a Combination Product	03/01/1998	
3	NDC:62391-100-30	960 g in 1 JAR; Type 0: Not a Combination Product	03/01/1998	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M017	03/01/1998	

Labeler - Health Care Laboratories Inc. (088637298)

Registrant - Health Care Laboratories Inc (088637298)

Establishment

Name	Address	ID/FEI	Business Operations
Health Care Laboratories Inc.		088637298	manufacture(62391-100)