

BIOACTIL- pain relieving gel
POLIMEROS Y SERVICIOS S.A.

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.

Submission for Bioactil Pain Relieving Gel

Detail showing Active Ingredient from package

Activeingredient.jpg

Drug Facts

Active ingredients

Menthol 3%.....

Purposes

Topical Analgesic

Information shown both on container label and package

Detail showing Inactive ingredient from package

Inactiveingredients.jpg

Inactive ingredients: carbomer, cetostearyl alcohol, cetostearyl ether, diazolidinyl urea, glycerin, methyl paraben, orthosilicic acid, phosphate buffer, propyl paraben, purified de-mineralized water, salicylic acid

Information shown both on container label and package

Detail showing Purpose within Active Ingredients from package

Purpose.jpg

Drug Facts

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Detail showing Instructions for use and named Uses from package

Uses.jpg

Uses:

Soothing relief from minor aches and pains of sore muscles & joints associated with ■ backache ■ arthritis ■ strains ■ sprains ■ bruises

Information shown both on container label and package

Detail showing Dosage and Administration within Directions from package

Directions.jpg

Directions: ■ Adults and children 12 years of age and older: apply to affected area not more than 3-4 times daily and gently massage until gel disappears. ■ Children under 12 years of age: do not use, consult a doctor.

Information shown both on container label and package

Detail showing Warnings from package

Warning.jpg

Warning:

■ For external use only. Use only as directed. ■ Avoid contact with eyes or mucous membranes. ■ Discontinue use if excessive irritation of the skin develops. ■ Do not bandage.

Information shown both on container label and package

Detail showing Keep Out of Reach of Children within Warnings from package

KeepoutofreachofchildrenBioactil.jpg

Keep out of reach of children to avoid accidental poisoning. If swallowed, get medical help or contact a Poison control Center right away.

Information shown on package and container label

Detail showing Questions from package

Questionsorcomments.jpg

Questions or comments? Call weekdays 9 am to 5 pm CST **1-888-621-1255** or **1-832-877-3784**

www.med-actil.com

Manufactured by Polimeros y Servicios, S.A. San Jose, Costa Rica • Distributed by Med-Actil, LLC., 1625 23rd St. Galveston, TX 77550



Information shown both on container label and package

Detail showing Other Information from package

OtherInformation.jpg

Other Information: Store at controlled room temperature 15° to 30°C (59° to 86°F). Lot No. Exp. Date: see box or see crimp of tube.

Information shown both on container label and package

Representative sample image of carton/container label

General view of inner container label

Keep out of reach of children to avoid accidental poisoning. If swallowed, get medical help or contact a Poison Control Center right away.

Directions: ■ Adults and children 2 years of age and older: apply to affected area not more than 3-4 times daily. ■ Children under 2 years of age: consult a doctor.

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Do Not Use if seal under cap is broken or missing.
This package contains an outer carton. Do not buy if outer carton is missing.



BIOACTIL

PAIN RELIEVING GEL



Hard-Working
Hard-Playing
Muscles & Joints
Deep Penetrating

Arthritis • Sprains & Strains
Exercise Empowerment
Sore Muscles & Joints
Workout Recovery
Backaches
Camphor Free

PLEASANT FRAGRANCE

Net Weight 2.46 oz (70 g)

NDC 69492-013-07

Drug Facts

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Menthol 3%.....

Uses:

Soothing relief from minor aches and pains of sore muscles & joints associated with ■ backache ■ arthritis ■ sprains ■ bruises

Warning:

■ For external use only. Use only as directed. ■ Avoid contact with eyes or mucous membranes. ■ Discontinue use if excessive irritation of the skin develops. ■ Do not bandage.

Allergy alert: ■ Certain persons can develop allergic reactions to ingredients in this product. If the symptom being treated does not subside or if redness, irritation, swelling, pain, or other symptoms develop or increase, discontinue use and consult a doctor.

Purposes

Topical Analgesic

Bioactil 6 frente.jpg

Bioactilfrente.jpg

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Topical Analgesic

General view of box content of labeling

Drug Facts

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Keep out of reach of children to avoid accidental poisoning. If swallowed, get medical help or contact a Poison Control Center right away.

Directions:

■ Adults and children 2 years of age and older; apply to affected area not more than 3-4 times daily.
■ Children under 2 years of age; consult a doctor.

Other Information: Store at controlled room temperature 15° to 30°C (59° to 86°F).

69492-013-07

Drug Facts (continued)

Inactive ingredients: carbomer, cetostearyl alcohol, cetostearyl ether, diazolidinyl urea, glycerin, methyl paraben, orthosilicic acid, phosphate buffer, propyl paraben, purified de-mineralized water, salicylic acid

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Backaches
Workout Recovery
Exercise Empowerment
Sore Muscles and Joints
Arthritis • Sprains & Strains

**Hard-Working, Hard-Playing
Muscles & Joints**

Lot & Exp.

PLEASANT FRAGRANCE

Camphor Free

Net Weight 2.46 oz (70 g)



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PLEASANT FRAGRANCE

Bioactilbox.jpg

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NDC 69492-013-07

Bioactil box.jpg

BIOACTIL			
pain relieving gel			
Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:69492-013
Route of Administration	TOPICAL		
Active Ingredient/Active Moiety			
	Ingredient Name	Basis of Strength	Strength
	MENTHOL (UNII: L7T10EIP3A) (MENTHOL - UNII:L7T10EIP3A)	MENTHOL	30 mg in 1 g
Inactive Ingredients			
	Ingredient Name		Strength

ALLANTOIN (UNII: 344S277G0Z)	
CARBOMER 940 (UNII: 4Q93RCW27E)	
CETOSTEARYL ALCOHOL (UNII: 2DMT128MIS)	
POLYOXYL 20 CETOSTEARYL ETHER (UNII: YRC528SWUY)	
DIAZOLIDINYL UREA (UNII: H5RIZ3MPW4)	
METHYLPARABEN (UNII: A2I8C7HI9T)	
ORTHOSILICIC ACID (UNII: 623B93YABH)	
SODIUM PHOSPHATE, DIBASIC (UNII: GR686LBA74)	
PROPYLPARABEN (UNII: Z8IX2SC1OH)	
SALICYLIC ACID (UNII: O414PZ4LPZ)	
WATER (UNII: 059QF0K00R)	

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:69492-013-07	1 in 1 BOX	03/12/2019	
1		70 g in 1 TUBE; 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	03/12/2019	

Labeler - POLIMEROS Y SERVICIOS S.A. (815740251)

Establishment			
Name	Address	ID/FEI	Business Operations
POLIMEROS Y SERVICIOS S.A.		815740251	manufacture(69492-013)