

BAROX BODY CARE MASSAGE- menthol gel
Dr.JangLab 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.

ACTIVE INGREDIENT

Active ingredient: Menthol 2%

INACTIVE INGREDIENT

Inactive ingredients:

Water, Alcohol, Propylene Glycol, Germanium Dioxide, Allantoin, Carbomer, Triethanolamine, PEG-60 Hydrogenated Castor Oil, Disodium EDTA, Methylparaben

PURPOSE

Purpose: Topical Analgesic

WARNINGS

Warnings: For external use only

KEEP OUT OF REACH OF CHILDREN

Keep out of reach of children:

Keep out of reach of children to avoid accidental ingestion.

If swallowed, get medical help or contact a Poison Control Center immediately.

USES

Uses:

Temporarily relieves the minor pains of muscles and joints associated with:
simple backache and arthritis

DOSAGE AND ADMINISTRATION

Dosage and administration:

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: ask a doctor

DESCRIPTION

Ask a doctor before use if you have redness over the affected area.

Do not use: on wounds or damaged skin

Stop use and ask a doctor if excessive skin irritation occurs.

Other information:

Store in a cool dry place with lid closed tightly

Question

Contact: smyou2@nate.com

PACKAGE LABEL. PRINCIPAL DISPLAY PANEL

The image shows the principal display panel of a Barox Body Care Massage Gel package. The background is a vibrant blue. On the left, the word "BAROX" is written in a large, light blue, sans-serif font. Below it, the text "Body Care Massage Gel" is written in white, followed by "Relax Refresh Recover" in a smaller white font. To the right of this text is a white circular icon depicting a person in a dynamic, athletic pose. On the right side of the panel, the word "BAROX" is repeated in a white, bold, sans-serif font, with a vertical white bar above it. Below this, the "Drug Facts" are listed in white text, including active and inactive ingredients, purpose, warnings, uses, and dosage information. At the bottom right, the volume "120ml" is printed in white, next to a white recycling symbol with the text "PLASTIC LDPE".

BAROX BODY CARE MASSAGE

menthol gel

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:55692-100
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name		Basis of Strength	Strength	
Menthol (UNII: L7T10EIP3A) (MENTHOL - UNII:L7T10EIP3A)		Menthol	2.4 mg in 120 mL	
Inactive Ingredients				
Ingredient Name			Strength	
WATER (UNII: 059QF0K00R)				
ALCOHOL (UNII: 3K9958V90M)				
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)				
Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:55692-100-01	120 mL in 1 TUBE		
Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
OTC monograph not final	part348	03/01/2012		

Labeler - Dr.JangLab Inc. (688380051)

Registrant - Dr.JangLab Inc. (688380051)

Establishment

Name	Address	ID/FEI	Business Operations
Dr.JangLab Inc.		688380051	manufacture(55692-100)

Revised: 2/2013

Dr.JangLab Inc.