

AY BENDITO - PAIN RELIEF- camphor, menthol cream
AY BENDITO INTERNATIONAL, 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.

72524-640-04

Camphor 6%

Menthol 4%

Topical Analgesic

Aid for temporary local relief of minor pain in muscles or joints.

For external use only.

Use only as directed

Do not bandage tightly or use with a heating pad

Avoid contact with eyes and mucous membranes

Do not apply to wounds or damaged, broken or irritated skin

A transient burning sensation or redness may occur upon application but generally disappears in several days

If you experience an allergic reaction, discontinue use and consult a physician

Do not expose the area treated with product to heat or direct sunlight.

STOP USE AND ASK A DOCTOR IF:

Condition worsens

Redness is present

Irritation develops

Symptoms persist for more than 7 days or clear up occur again within a few days

You experience signs injury, such as pain, swelling or blistering where the product was applied.

IF PREGNANT OR BREAST – FEEDING:

Ask a health professional before use.

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

DIRECTIONS:

Adults and Children over 12 years of age:

Apply a small amount on the affected area.

Massage in circular motion, let set for a few seconds.

Repeat as necessary, but no more than 3 to 4 times daily.

Children under 12 years of age: do not use, consult a doctor.

OTHER INFORMATION

Store tightly closed in a dry place at controlled room temperature between 59°-86° F (15°-30° C).

Water (Aqua), Alcohol Denat, Glycerin, Paraffinum Liquidum, Triethanolamine, Arnica Montana Flower Extract, Polysorbate 20, Carbomer, Methyl Salicylate, Sodium Chondroitin Sulfate, Glucosamine Sulfate, Rosmarinus Officinalis (Rosemary) Extract, Methylchlorisothiazolinone, Methylisothiazolinone, FD&C Blue No.1 (CI 42090).

QUESTION OR COMMENTS?

Call: +1-787-421-6423

AY BENDITO THERMOACTIVE CREAM

Drug Facts (continued)

Warnings

- Do not use if you have ever had an allergic reaction to any of the ingredients.
- Do not use if you are pregnant or breastfeeding.
- Do not use if you are allergic to any of the ingredients.
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Directions

Apply a small amount to the affected area. Rub gently into the skin. Use 3-4 times daily. Do not use more than 12 times daily. Do not use on open wounds.

Other information

Keep tightly closed in a dry place at controlled room temperature between 59°-86° F (15°-30° C).

Contains: Water (Aqua), Alcohol Denat, Glycerin, Paraffinum Liquidum, Arnica Montana Flower Extract, Polysorbate 20, Carbomer, Methyl Salicylate, Sodium Chondroitin Sulfate, Rosmarinus Officinalis (Rosemary) Extract, Methylchlorisothiazolinone, Methylisothiazolinone, FD&C Blue No.1 (CI 42090).

Distributed by:
Ay Bendito International, Inc.
15000 Hwy 270, Ok. Blvd., Ft. 35172, USA
Email: aybendito@gmail.com
www.aybendito.com

AY BENDITO

THERMOACTIVE CREAM

Fast Acting Muscle and Joint Pain Relief

IMMEDIATE ACTION

EXTERNAL USE ONLY

Net wt. 4 oz (113.4 g)

Drug Facts

Active ingredients: Methyl Salicylate, Menthol, Camphor, Eucalyptus, Thymol, Clove Oil, Peppermint Oil, Wintergreen Oil, Tea Tree Oil, Lavender Oil, Chamomile Oil, Calendula Oil, Aloe Vera Gel, Vitamin E, and Natural Fragrance.

Warnings:

- Do not use if you are pregnant or breastfeeding.
- Do not use if you are allergic to any of the ingredients.
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Directions:

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THERMOACTIVE CREAM

Fast Acting Muscle and Joint Pain Relief

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EXTERNAL USE ONLY

Net wt. 4 oz (113.4 g)

AY BENDITO - PAIN RELIEF

camphor, menthol cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:72524-640
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
MENTHOL, (+)- (UNII: C6B10E8P3W) (MENTHOL, (+)- - UNII:C6B10E8P3W)	MENTHOL, (+)-	4 g in 100 g
CAMPHOR (NATURAL) (UNII: N20HL7Q941) (CAMPHOR (NATURAL) - UNII:N20HL7Q941)	CAMPHOR (NATURAL)	6 g in 100 g

Inactive Ingredients

Ingredient Name	Strength
MINERAL OIL (UNII: T5L8T28FGP)	
TROLAMINE (UNII: 9O3K93S3TK)	
WATER (UNII: 059QF0KO0R)	
GLYCERIN (UNII: PDC6A3C0OX)	
ARNICA MONTANA WHOLE (UNII: O80TY208ZW)	
GLUCOSAMINE SULFATE (UNII: 1FW7WLR731)	
SODIUM CHONDROITIN SULFATE (PORCINE; 5500 MW) (UNII: H5BJH23Z9A)	
METHYLCHLOROISOTHIAZOLINONE (UNII: DEL7T5QRPN)	
METHYLISOTHIAZOLINONE (UNII: 229D0E1QFA)	
POLYSORBATE 20 (UNII: 7T1F30V5YH)	
METHYL SALICYLATE (UNII: LAV5U5022Y)	
ROSMARINUS OFFICINALIS FLOWERING TOP (UNII: 8JM482TI79)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
CARBOMER 940 (UNII: 4Q93RCW27E)	

Product Characteristics

Color	blue	Score	
Shape		Size	
Flavor		Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:72524-640-04	113 g in 1 JAR; Type 0: Not a Combination Product	01/22/2021	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part348	01/22/2021	

Registrant - CHEMCO CORPORATION (032495954)

Establishment

Name	Address	ID/FEI	Business Operations
CHEMCO CORPORATION		032495954	manufacture(72524-640)

Revised: 7/2023

AY BENDITO INTERNATIONAL, INC