

AY BENDITO - THERMOACTIVE- camphor, menthol gel
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.

72524-604-04

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.

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.

KEEP OUT OF REACH OF CHILDREN:

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

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, Arnica Montana Flower Extract, Triethanolamine, Polysorbate 20, Carbomer, Methyl Salicylate, Sodium Chondroitin Sulfate, Glucosamine Sulfate, Rosmarinus Officinalis (Rosemary) Extract, Methylchloroithiazolinone, Methylisothiazolinone, FD&C Blue No.1 (CI 42090).

QUESTION OR COMMENTS?

Call: +1-787-421-6423

AY BENDITO THERMOACTIVE GEL

Drug Facts

Active ingredients	Purpose
Camphor..... 6%	Topical analgesic
Menthol..... 4%	Topical analgesic

Uses
Aid for temporary relief of minor pains of muscles or joints.

Warnings
For external use only.

When using this product

- 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 doctor.
- 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.

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

EXTERNAL USE ONLY
Net wt. 4 Oz (113.4 g)
NDC# 72524-604-04

Drug Facts (continued)

Directions
Adults and Children over 12 years of age

- Apply in 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).

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

Question or comments?
Call: +1-787-421-6423

Distributed by:
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AY BENDITO - THERMOACTIVE

camphor, menthol gel

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:72524-604
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
WATER (UNII: 059QF0KO0R)	
GLYCERIN (UNII: PDC6A3C0OX)	
ARNICA MONTANA FLOWER WATER (UNII: U7L2JP51PR)	
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)	
TROLAMINE (UNII: 9O3K93S3TK)	
ALCOHOL (UNII: 3K9958V90M)	
MINERAL OIL (UNII: T5L8T28FGP)	

Product Characteristics

Color	blue	Score	
Shape		Size	
Flavor		Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:72524-604-04	90 g in 1 BOTTLE, PUMP; 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	

Labeler - AY BENDITO INTERNATIONAL, INC (081332094)

Registrant - CHEMCO CORPORATION (032495954)

Establishment

Name	Address	ID/FEI	Business Operations
CHEMCO CORPORATION		032495954	manufacture(72524-604)

Revised: 7/2023

AY BENDITO INTERNATIONAL, INC