

AY BENDITO - CBD- 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.

72524-009-04
72524-009-17

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 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.

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 - CBD ROLL ON

Drug Facts

Active Ingredients

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 recur upon application 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.

Drug Facts (continued)

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).

Inactive Ingredients
Water (Aqua), Alcohol Denat, Glycerin, Paraffinum Liquidum, Camphor, Salicylic Acid, Arnica Montana Flower Extract, Triethanolamine, Carbomer, Camphor, Methyl Salicylate, Glucosamine Sulfate, Sodium Chondroitin Sulfate, Rosmarinus Officinalis (Rosemary) Extract, Methylchlorisothiazolinone, Methylisothiazolinone, FD&C Blue #1 Powder (CI 42090), FD&C Yellow #5 (CI 19140).

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

Distributed by:
Ay Bendito International, Inc.
10636 New 27th St, Doris, FL 33172, USA
Email: aybendito@gmail.com
www.aybendito.com

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AY BENDITO - CBD SACHET

Ay Bendito!
CBD Oil
Cannabis sativa Plus
 • Menthol
 • Camphor
Fast Pain Relief!
 EXTERNAL USE ONLY
 Net wt. 0.17 Oz (5 mL)
 NDC# 72524-009-17

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 damage jewelry 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 no occur again within a few days.
 • The experience signs injury such as pain, swelling or redness where the product was applied.

Drug Facts (continued)
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.
Directions
 Adults and children over 12 years of age
 • Apply a small amount on the affected area.
 • Massage in circular motion, but not more than 3 to 4 times daily.
 • 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 (Aque), Alcohol Denat, Glycerin, Panthenol Liquidum, Cannabis Sativa Seed Oil, Arica Montana Flower Extract, Triethanolamine, Camphor, Camphorol, Methyl Salicylate, Glucosamine Sulfate, Sodium Chondroitin Sulfate, Rosmarinus Officinalis (Rosemary) Extract, Methylchloroisothiazolinone, Methylisothiazolinone, FD&C Blue #1 Powder (CI 42000), FD&C Yellow #5 (CI 19140).
Question or comments?
 Call: +1-787-421-6423

Distributed by:
 Ay Bendito International, Inc.
 14001 SW 77th St, Suite 111, 33193, USA
 Email: aybendito@aybendito.com
 www.aybendito.com

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AY BENDITO - CBD

camphor, menthol gel

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:72524-009
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
MENTHOL (UNII: L7T10EIP3A) (MENTHOL - UNII:L7T10EIP3A)	MENTHOL	4 g in 100 g
CAMPHOR (SYNTHETIC) (UNII: 5TJD82A1ET) (CAMPHOR (SYNTHETIC) - UNII:5TJD82A1ET)	CAMPHOR (SYNTHETIC)	6 g in 100 g

Inactive Ingredients

Ingredient Name	Strength
TROLAMINE (UNII: 903K93S3TK)	
GLUCOSAMINE SULFATE (UNII: 1FW7WLR731)	
WATER (UNII: 059QF0KO0R)	

GLYCERIN (UNII: PDC6A3C0OX)	
ARNICA MONTANA FLOWER (UNII: OZ0E5Y15PZ)	
SODIUM CHONDROITIN SULFATE (PORCINE; 5500 MW) (UNII: H5BJH23Z9A)	
METHYLCHLOROISOTHIAZOLINONE (UNII: DEL7T5QRPN)	
METHYLISOTHIAZOLINONE (UNII: 229D0E1QFA)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
POLYSORBATE 20 (UNII: 7T1F30V5YH)	
METHYL SALICYLATE (UNII: LAV5U5022Y)	
ROSMARINUS OFFICINALIS WHOLE (UNII: EA3289138M)	
CARBOMER 940 (UNII: 4Q93RCW27E)	
MINERAL OIL (UNII: T5L8T28FGP)	
ALCOHOL (UNII: 3K9958V90M)	
CANNABIDIOL (UNII: 19GBJ60SN5)	
FD&C YELLOW NO. 5 (UNII: I753WB2F1M)	
CANNABIS SATIVA SEED OIL (UNII: 69VJ1LPN1S)	

Product Characteristics

Color	green (Light)	Score	
Shape		Size	
Flavor		Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:72524-009-04	90.15 g in 1 BOTTLE; Type 0: Not a Combination Product	09/08/2023	
2	NDC:72524-009-17	5 g in 1 PACKET; Type 0: Not a Combination Product	09/08/2023	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part348	09/08/2023	

Labeler - AY BENDITO INTERNATIONAL, INC (081332094)