

AY BENDITO - THERMOACTIVE- 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.

72524-641-04

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 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.

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, Methylchloroisothiazolinone, Methylisothiazolinone, FD&C Blue No.1 (CI 42090).

QUESTION OR COMMENTS?

Call: +1-787-421-6423

AY BENDITO THERMOACTIVE CREAM TUBE



AY BENDITO - THERMOACTIVE			
camphor, menthol cream			
Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:72524-641
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety				
Ingredient Name			Basis of Strength	Strength
CAMPHOR (NATURAL) (UNII: N20HL7Q941) (CAMPHOR (NATURAL) - UNII:N20HL7Q941)			CAMPBOR (NATURAL)	6 g in 100 g
MENTHOL, (+)- (UNII: C6B1OE8P3W) (MENTHOL, (+)- - UNII:C6B1OE8P3W)			MENTHOL, (+)-	4 g in 100 g
Inactive Ingredients				
Ingredient Name				Strength
TROLAMINE (UNII: 9O3K93S3TK)				
MINERAL OIL (UNII: T5L8T28FGP)				
WATER (UNII: 059QF0K00R)				
GLYCERIN (UNII: PDC6A3C0OX)				
ARNICA MONTANA FLOWER WATER (UNII: U7L2JP51PR)				
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)				
GLUCOSAMINE SULFATE (UNII: 1FW7WLR731)				
Product Characteristics				
Color		blue	Score	
Shape			Size	
Flavor			Imprint Code	
Contains				
Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:72524-641-04	113 g in 1 TUBE; 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(72524-641)

Revised: 7/2023

AY BENDITO INTERNATIONAL, INC