

PAINZAWAY BALM- camphor ointment
Indiana Botanic Gardens

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.

Painzaway Balm

Active Ingredient

Camphor 4.0%

Purpose

external analgesic ointment

Uses:

Temporary relief of minor aches and pains of muscles and joints associated with arthritis, strains, bruises or simple backache.

Warnings

For external use only.

Avoid contact with the eyes.

When using this product, do not:

heat

microwave

use near open flames

add to hot water or any container where heating water.

May cause splattering and result in burns.

Do Not

use on wounds or damaged skin

bandage tightly

Stop using and ask a doctor if

condition worsens, or if symptoms persist for more than 7 days or clear up and occur again within a few days.

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

Directions

Adults and children 2 years of age and older: apply to affected area not more than 3 to 4 times daily.

Children under 2 years of age: consult physician.

Other information

Any Questions? 1-800-644-8327

website: www.botanicchoice.com

Use only if seal is unbroken.

Inactive ingredients

White petrolatum, cassia oil, clove oil, siberian fir needle oil, cajeput oil, peppermint oil, natural beeswax.

Manufactured by: Indiana Botanic Gardens, Inc.

3401 W. 37th Avenue Hobart, IN 46342

Painzaway Balm

Topical Analgesic

Net Wt. 2oz.



PAINZAWAY BALM			
camphor ointment			
Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:10578-040
Route of Administration	TOPICAL		
Active Ingredient/Active Moiety			
Ingredient Name		Basis of Strength	Strength
CAMPHOR (SYNTHETIC) (UNII: 5TJD82A1ET) (CAMPHOR (SYNTHETIC) - UNII:5TJD82A1ET)		CAMPHOR (SYNTHETIC)	4 g in 100 g
Inactive Ingredients			

Ingredient Name	Strength
PETROLATUM (UNII: 4T6H12BN9U)	
ABIES SIBIRICA LEAF OIL (UNII: XRY0V4VZKZ)	
CAJUPUT OIL (UNII: J3TO6BUQ37)	
CHINESE CINNAMON OIL (UNII: A4WO0626T5)	
CLOVE LEAF OIL (UNII: VCA5491KVF)	
PEPPERMINT OIL (UNII: AV092KU4JH)	
YELLOW WAX (UNII: 2ZA36H0S2V)	

Product Characteristics

Color	YELLOW	Score	
Shape		Size	
Flavor		Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:10578-040-01	29 g in 1 JAR; Type 0: Not a Combination Product		
2	NDC:10578-040-02	57 g in 1 JAR; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part348	12/01/2001	

Labeler - Indiana Botanic Gardens (005421771)

Establishment

Name	Address	ID/FEI	Business Operations
Indiana Botanic Gardens		005421771	manufacture(10578-040)

Revised: 10/2015

Indiana Botanic Gardens