TOPICAL ANALGESIC- dermaline camphor ointment
Dermaline USA Corp

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.

Dermaline Camphor Ointment

This is a hand sanitizer manufactured according to the Temporary Policy for Preparation of Certain Alcohol-Based Hand Sanitizer Products During the Public Health Emergency (CoViD-19); Guidance for Industry.

The hand sanitizer is manufactured using only the following United States Pharmacopoeia (USP) grade ingredients in the preparation of the product (percentage in final product formulation) consistent with World Health Organization (WHO) recommendations:

a. Alcohol (ethanol) (USP or Food Chemical Codex (FCC) grade) (80%, volume/volume (v/v)) in an aqueous solution denatured according to Alcohol and Tobacco Tax and Trade Bureau regulations in 27 CFR part 20.
b. Glycerol (1.45% v/v).
c. Hydrogen peroxide (0.125% v/v).
d. Sterile distilled water or boiled cold water.

The firm does not add other active or inactive ingredients. Different or additional ingredients may impact the quality and potency of the product.

Active Ingredient(s)

Camphor 10%. Purpose: Topical Analgesic

Purpose

Topical Analgesic

Use

For temporary relief of minor aches and pains of muscles and joints associated with simple backache, arthritis, strains, bruises and sprains.

Warnings

For external use only. Flammable. Avoid contact with the eyes. Do not bandage tightly or apply to wounds or damaged skin.

Do not use

On children under 16 years of age except on the advice of a physician.

When using this product keep out of eyes, ears, and mouth. In case of contact with eyes, rinse eyes thoroughly with water.
Stop use and ask a doctor if irritation or rash occurs. These may be signs of a serious condition.
Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.

Stop use and ask a doctor if condition worsens, or if symtpoms 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 16 years of age and older. Wash the affected area with mild soap and warm water and rinse thorougly. Apply to affected area not more than 3 to 4 times a day.

Other information

- Store between 15-30C (59-86F)
- Do not expose to excessive heat

Inactive ingredients

cyclomethicone, white petrolatum

Package Label - Principal Display Panel

70g NDC: 82165-103-02

TOPICAL ANALGESIC

dermaline camphor ointment

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:82165-103
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
CAMPHOR (SYNTHETIC) (UNII: 5TJD82A1ET) (CAMPHOR (SYNTHETIC) - UNII:5TJD82A1ET)	CAMPHOR (SYNTHETIC)	10 g in 100 g

Inactive Ingredients	
Ingredient Name	**Strength**
WHITE PETROLATUM (UNII: B6E5W8RQJ4)	
CYCLOMETHICONE (UNII: NMQ347994Z)	

Product Characteristics			
Color	white	**Score**	
Shape		**Size**	
Flavor		**Imprint Code**	
Contains			

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:82165-103-02	70 g in 1 JAR; Type 0: Not a Combination Product	03/27/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part348	05/12/2019	

Labeler - Dermaline USA Corp (016069241)

Establishment

Name	Address	ID/FEI	Business Operations
World Perfumes Inc		101312044	manufacture(82165-103)

Revised: 2/2023 Dermaline USA Corp