

NATUREANCE MIRACLE- menthol oil
EROS GLOBAL 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.

80465-008-01

Menthol 8%

Topical Analgesic

USES:

Aid for temporary local relief of minor pain in muscles or joints.

For external use only.

Avoid contact with the eyes or mucous membranes.

Do not apply to wounds or damaged skin.

Do not apply to the irritated skin or if excessive irritation develops.

Do not bandage.

Do not use with heating pad or device.

Stop use 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 away from fire or flame.

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:

Apply a small amount on the area to be.

Massaged in a 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: Consult physician.

OTHER INFORMATION:

Store in a cool dry place with lid closed tightly.

Isopropyl Myristate, Parfum, Limonene.



NATUREANCE

Miracle Oil

aceite milagroso

1 fl. oz. (30 mL)

Miracle Oil



7 55439 35079 9

NDC# 80465-008-01

Drug Facts

Active Ingredient: Menthol... 5% Topical Analgesic

Uses: Aid for temporary local relief of minor pain in muscles or joints.

Warnings: For external use only.

When using this product: Avoid contact with the eyes or mucous membranes. Do not apply to wounds or damaged skin. Do not apply to the irritated skin or if excessive irritation develops. Do not bandage or use with heating pad or device. Stop use and ask a doctor if symptoms persist for more than 7 days, or if rash, hives, or other allergic reactions occur within a few days.

Flammable: Keep away from fire or flame.

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 old: Apply a small amount on the area to be treated. Massage in a circular motion, for relief for up to 4 hours. Children under 12 years of age: Consult physician.

Other information: Store in a cool dry place with lid closed tightly.

Inactive Ingredients: Isopropyl Myristate, Parfums, Limonene.

Distributed by Eros Global Corp | Houston, TX 77092
www.natureance.com



NATUREANCE MIRACLE			
menthol oil			
Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:80465-008
Route of Administration	TOPICAL		
Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
MENTHOL (UNII: L7T10EIP3A) (MENTHOL - UNII:L7T10EIP3A)	MENTHOL	8 g in 100 g	
Inactive Ingredients			
Ingredient Name	Strength		
ISOPROPYL MYRISTATE (UNII: 0RE8K4LNJS)			
LIMONENE, (+)- (UNII: GFD7C86Q1W)			
Packaging			
	Marketing Start	Marketing End	

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:80465-008-01	28.4 g in 1 BOTTLE; Type 0: Not a Combination Product	09/19/2020	
Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
OTC monograph not final	part348	09/19/2020		

Labeler - EROS GLOBAL CORP (117597821)

Revised: 10/2022

EROS GLOBAL CORP