

CETILAR- menthol 1.4% cream
PharmaNutra Usa Corp.

Cetilar

Active Ingredient

Menthol 1.4%

Purpose

Topical Analgesic

Use

For the 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. Avoid contact with eyes

When using this product

- Do not bandage tightly
- do not apply to wounds or damage skin

Stop use and ask a doctor

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

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:

- Apply to the affect area not more than 3 to 4 times daily
- After applying, wash hands with soap and water

Children 12 years or younger, consult a doctor

Other Information

The product must be stored at temperature between 50-86 °F (10-30°C), in a dry place away from light localized heat sources.

Inactive ingredients

water, cetyl myristate, Glycerin, Cetyl alcohol, Glyceryl stearate, olea europea (olive) oil unsaponifiables, cetyloleate, Butylene glycol, Caprylic capric triglyceride, prunus armeniaca (apricot) kernel oil, Beeswax, Phenoxyethanol, Triethanolamine, carbomer, fragrance, isopropyl myristate, ethylhexylglycerin, triticum vulgare (wheat) germ oil, BHT, tocopheryl acetate.

Artwork Information Panel				
Customer Blofarma s.r.l.		Date 01.08.2024	Draft 0	
Product Type Folding Cartons	Product Name/Trade Name CAMPIONATURA ASTUCCI ANONIMA FORMATO 35X35X175 MM			
Code ANON_35X35X175	Bill of Material -	Technical Specifications -		
Material TAMBRITE	Die cut Drawing Code BM0505	Die cut Code BM0505	Internal Dimension (mm) 35x35x175	Grammage (g/m²) 270 gr.
Colors (Pantone) UV Lucida FUSTELLA 				

PALLADIO GROUP
Packaging Clinic

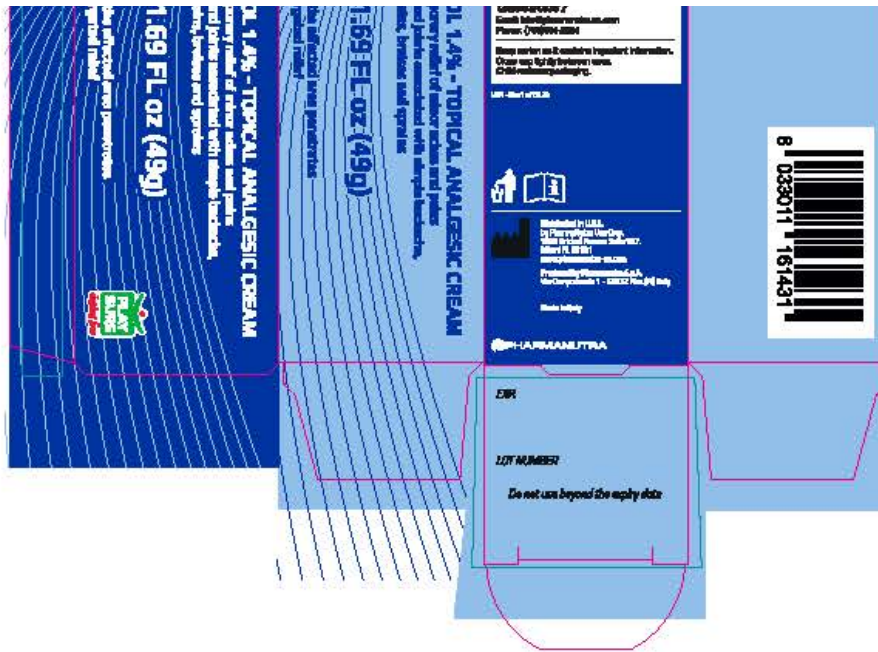
PRINT APPROVAL

Date: _____

Signature: _____

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CETILAR

menthol 1.4% cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:84797-000
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
MENTHOL (UNII: L7T10EIP3A) (MENTHOL - UNII:L7T10EIP3A)	MENTHOL	1.4 g in 100 g

Inactive Ingredients

Ingredient Name	Strength
GLYCERIN (UNII: PDC6A3C0OX)	
BUTYLENE GLYCOL (UNII: 3XUS85K0RA)	
APRICOT SEED OIL (UNII: 54JB35T06A)	
WATER (UNII: 059QF0KO0R)	
GLYCERYL STEARATE (UNII: 230OU9XXE4)	
PHENOXYETHANOL (UNII: H1E492ZZ3T)	
.ALPHA.-TOCOPHEROL ACETATE, D- (UNII: A7E6112E4N)	
CAPRYLIC/CAPRIC TRIGLYCERIDE (UNII: C9H2L21V7U)	
TRIETHANOLAMINE (UNII: 9O3K93S3TK)	
WHEAT GERM OIL UNSAPONIFIABLES (UNII: 6AXM7XCV3D)	
BEESWAX (UNII: 2ZA36H0S2V)	
POLYACRYLIC ACID (8000 MW) (UNII: 73861X4K5F)	
CETYL ALCOHOL (UNII: 936JST6JCN)	

BUTYLATED HYDROXYTOLUENE (UNII: 1P9D0Z171K)	
CETYL MYRISTATE (UNII: 7OPL833Q4D)	
PERFLUOROPOLYMETHYLISOPROPYL ETHER (UNII: X6324K3MBW)	
ISOPROPYL MYRISTATE (UNII: 0RE8K4LNJS)	
ETHYLHEXYLGLYCERIN (UNII: 147D247K3P)	

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:84797-000-49	1 in 1 CARTON	02/01/2025	
1		49 g in 1 TUBE; Type 0: Not a Combination Product		

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M017	02/01/2025	

Labeler - PharmaNutra Usa Corp. (119066016)

Establishment			
Name	Address	ID/FEI	Business Operations
Biofarma SRL		507836496	manufacture(84797-000)

Revised: 2/2025

PharmaNutra Usa Corp.