EXTERNAL ANALGESIC CREAM WITH MENTHOL 5%- menthol 5% cream BLOOMWELL GARDENS LLC

Active ingredient

Menthol 5%

Water, Propylene Glycol, Carbomer Homopolymer, Glycerin,

Edetate Disodium, Hydroxyacetophenone, 1,2-Hexanediol,

Mentha Arvensis Leaf, Chrysanthemum Indicum Top,

Portulaca, Polyoxyl 40 Hydrogenated Castor Oil

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

For external use only

avoid contact with eyes,

mucous membranes do not bandage tightly

Stop use and ask a doctor if: condition worsens

symptoms persist for more than 7 days

symptoms 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

If pregnant or breastfeeding, ask a health professional before use

- Adults and children 12 years and older:

Clean the affected area with mild soap and warm water, then pat dry.

Apply a thin, even layer to the affected area not more than 3 to 4 times daily.

- Children under 12 years: consult a doctor

Temporary relief of minor aches and pains

on wounds or damaged skin with a heating pad

if allergic to menthol or any ingredient in this product

Store at 15–30°C (59–86°F)

Protect from excessive moisture and direct sunlight

Keep the carton for full labeling

Flammable: keep away from fire or flame



Instruction

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EXTERNAL ANALGESIC CREAM WITH MENTHOL 5%

menthol 5% cream

Product Information

Product Type HUMAN OTC DRUG Item Code (Source) NDC:85284-010

Route of Administration TOPICAL

Active Ingredient/Active Moiety

Ingredient Name

Basis of Strength

MENTHOL (UNII: L7T10EIP3A) (MENTHOL - UNII:L7T10EIP3A)

MENTHOL

5 g in 100 g

Inactive Ingredients Ingredient Name Strength HYDROXYACETOPHENONE (UNII: G1L3HT4CMH) WATER (UNII: 059QF0K00R) POLYOXYL 40 HYDROGENATED CASTOR OIL (UNII: 7YC686GQ8F) PORTULACA GRANDIFLORA LEAF (UNII: VHJ480553K) PROPYLENE GLYCOL (UNII: 6DC9Q167V3) CARBOMER HOMOPOLYMER, UNSPECIFIED TYPE (UNII: 0A5MM307FC) GLYCERIN (UNII: PDC6A3C0OX) EDETATE DISODIUM (UNII: 7FLD91C86K) CHRYSANTHEMUM INDICUM TOP (UNII: 607YAE70V1) MENTHA ARVENSIS LEAF (UNII: A4IWO4DDZ9)

1,2-HEXANEDIOL	(LINII) TROA6Y3K1G	
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Packaging						
#	Item Code	Package Description	Marketing Start Date	Marketing End Date		
1	NDC:85284-010- 01	50 g in 1 BOTTLE; Type 0: Not a Combination Product	10/02/2025			

Marketing Information						
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date			
OTC Monograph Drug	M017	10/02/2025				

Labeler - BLOOMWELL GARDENS LLC (124839891)

Establishment								
Name	Address	ID/FEI	Business Operations					
Jiangxi Hemei Pharmaceutical Co., Ltd.		724892056	manufacture(85284-010)					

Revised: 10/2025 BLOOMWELL GARDENS LLC