

DOLOFLEX PAIN RELIEF- menthol, methyl salicylate gel

United Health & Beauty Corp

Doloflex Pain Relief

Menthol 2%, Methyl Salicylate 10%

Topical Analgesic

Temporarily relieves the minor aches and pain of muscles and joints associated with simple backache, arthritis, strains, sprains, and bruises.

For external use only.

Do not use on children under 12 years of age, with a heating pad (may blister skin), on wounds or damaged skin.

When using this product do not bandage tightly, avoid contact with the eyes or mucous membranes.

Stop use and ask a doctor if excessive irritation develops, symptoms last more than 7 days or clear up and occur again within a few days, condition worsens.

If swallowed, get medical help or contact a poison control center right away.

Adults and children 12 years of age or older: apply to affected area up to 3 to 4 times daily. Children under 12 years of age: consult a physician.

Water, alcohol, carbomer, DMDM Hydantoin, Iodopropynyl Butylcarbamate, PEG-40 Hydrogenated Caster Oil, Aesculus Hippocastanum Seed Extract, Centella Asiatica Leaf Extract, Arnica Montana Flowers Oil, Calendula Officinalis Flower Extract, Triethanolamine.

DRUG FACTS		STOP USE AND ASK A DOCTOR IF
ACTIVE INGREDIENT	PURPOSE	• Excessive irritation develops • symptoms last more than 7 days or clear up and occur again within a few days • conditions worsen
Menthol 2% Methyl Salicylate 10%	Topical analgesic Topical analgesic	KEEP OUT OF REACH OF CHILDREN. If swallowed, get medical help or contact a poison control center right away.
USES	Temporarily relieves the minor aches and pains of muscles and joints associated with • Simple backache • Arthritis • Strains • Sprains • Bruises	DIRECTIONS • adults & children 12 years of age or older: apply to affected area up to 3 to 4 times daily. • children under 12 years of age: consult a physician.
WARNINGS	For External Use Only DO NOT USE ON • On children under 12 years of age • With a heating pad (may blister skin) • On wounds or damage skin	OTHER INFORMATION STORE BETWEEN 20° - 30°C (60° - 86°F)
WHEN USING THIS PRODUCT	do not bandage tightly • avoid contact with the eyes or mucous membranes.	INACTIVE INGREDIENTS: water, alcohol, camphor, carbomer, DMAD Hyaluron, Iodopropynyl Butylcarbamate, PEG-40 Hydrogenated Castor Oil, Aesculus Hippocastanum Seed Extract, Centella Asiatica Leaf Extract, Arnica Montana Flowers Oil, Calendula Officinalis Flower Extract, Triethanolamine.

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MADE IN COLOMBIA

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DOLOFLEX PAIN RELIEF

menthol, methyl salicylate gel

Product Information

Product Type

HUMAN OTC DRUG

Item Code (Source)

NDC:85350-039

Route of Administration TOPICAL

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
MENTHOL (UNII: L7T10EIP3A) (MENTHOL - UNII:L7T10EIP3A)	MENTHOL	2 g in 100 g
METHYL SALICYLATE (UNII: LAV5U5022Y) (SALICYLIC ACID - UNII:O414PZ4LPZ)	METHYL SALICYLATE	10 g in 100 g

Inactive Ingredients

Ingredient Name	Strength
ARNICA MONTANA FLOWER (UNII: OZ0E5Y15PZ)	
PEG-40 HYDROGENATED CASTOR OIL (UNII: 7YC686GQ8F)	
DMDM HYDANTOIN (UNII: BYR0546TOW)	
HORSE CHESTNUT (UNII: 3C18L6RJAZ)	
CALENDULA OFFICINALIS FLOWER (UNII: P0M7O4Y7YD)	
CAMPHOR (SYNTHETIC) (UNII: 5TJD82A1ET)	
IODOPROPYNYL BUTYLCARBAMATE (UNII: 603P14DHEB)	
TRIETHANOLAMINE (UNII: 9O3K93S3TK)	
WATER (UNII: 059QF0KO0R)	
ALCOHOL (UNII: 3K9958V90M)	
CENTELLA ASIATICA LEAF (UNII: 6810070TYD)	
CARBOMER 940 (UNII: 4Q93RCW27E)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:85350-039-10	300 g in 1 JAR; Type 0: Not a Combination Product	03/17/2025	
2	NDC:85350-039-11	300 g in 1 JAR; Type 0: Not a Combination Product	09/30/2025	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M017	03/17/2025	

Labeler - United Health & Beauty Corp (087150432)

Registrant - Maximsuramerica SAS (886586033)

Establishment

Name	Address	ID/FEI	Business Operations
Maximsuramerica SAS		886586033	manufacture(85350-039)

