OPRAVA- methyl salicylate, menthol, capsaicin cream Biological M.D. Solutions LLC

BIOLOGICAL MD SOLUTIONS (as PLD) - OPRAVA (83538-102)

ACTIVE INGREDIENTS

METHYL SALICYLATE 10%
MENTHOL 1%
CAPSAICIN 0.03%

PURPOSE

FOR TEMPORARY PAIN RELIEF

USES

TEMPORARILY RELIEVES

- ARTHRITIS
- MUSCLE PAIN
- INFLAMMATION

WARNING

FOR EXTERNAL USE ONLY.

- AVOID CONTACT WITH EYES, MUCOUS MEMBRANES AND BROKEN OR IRRITATED SKIN.
- IF CONDITION WORSENS, OR IF SYMPTOMS PERSIST FOR MORE THAN 7 DAYS, OR IF REDNESS IS PRESENT, DISCONTINUE USE AND CONSULT A PHYSICIAN.

USE ONLY AS DIRECTED.

NOT FOR USE IN CHILDREN UNDER 12 YEARS OF AGE.

KEEP OUT OF REACH OF CHILDREN. IF SWALLOWED, SEEK PROFESSIONAL ASSISTANCE OR CALL A POISON CONTROL CENTER IMMEDIATELY.

DIRECTIONS

- APPLY GENEROUSLY.
- GENTLY MASSAGE INTO PAINFUL AREA UNTIL THOROUGHLY ABSORBED.
- REPEAT AS NECESSARY, UP TO FOUR TIMES DAILY.
- PRODUCT CAN BE USED WITH A WRAP.

STORE AT CONTROLLED ROOM TEMPERATURE. 59° - 86°F (15° - 30°C).

INACTIVE INGREDIENTS

ALOE VERA, VITAMINS A AND E, ANTIOXIDANTS, ALOE BARBADENSIS LEAF JUICE, BORAGE OIL, CARBOMER, CETEARYL ALCOHOL, CETYL ALCOHOL, DEIONIZED WATER, EUCALYPTUS GLOBULUS LEAF OIL, FRUCTOSE, LAVANDULA ANGUSTIFOLIA (LAVENDER) OIL, METHYL PARABEN, OLEA EUROPAEA (OLIVE) FRUIT OIL, PHENOXYETHANOL, POLYSORBATE-60, PROPYL PARABEN, PROPYLENE GLYCOL, SALMON OIL, SODIUM HYDROXIDE, SQUALANE, STEARYL ALCOHOL, STEARIC ACID, TETRASODIUM EDTA, TOCOPHEROL, TOCOPHERYL ACETATE, VITIS VINIFERA (GRAPE) SEED OIL



Drug Facts

Active Ingredients Purpose
Methyl salicylate 10% For temporary
Menthol 1% pain relief
Capsaicin .03%

Use temporarily relieves

- Arthritis
 - Muscle Pain
- Inflammation

Warning For external use only.

When Using This Product

- Avoid contact with eyes, mucous membranes and broken or irritated skin.
- If condition worsens, or if symptoms persist for more than 7 days, or if redness is present, discontinue use and consult a physician.

Use only as directed.

Not for use in children under 12 years of age.

Keep out of reach of children. If swallowed, seek professional assistance or call a Poison Control Center immediately.

Manufactured in the USA by:

Biological MD Solutions Bellevue, WA 98005

MU SOLUTIONS EXPIRES:

LOT:

Drug Facts (continued)

Directions

- Apply generously.
- Gently massage into painful area until thoroughly absorbed.
- Repeat as necessary, up to four times daily.
- Product can be used with a wrap.

Other Information Store at controlled room temperature. 59°-86°F (15°-30°C).

Inactive Ingredients

Aloe Vera, Vitamins A and E, Antioxidants, Aloe Barbadensis Leaf Juice, Borage Oil, Carbomer, Cetearyl Alcohol, Cetyl Alcohol, Deionized water, Eucalyptus Globulus Leaf Oil, Fructose, Lavandula Angustifolia (Lavender) Oil, Methyl Paraben, Olea Europaea (Olive) Fruit Oil, Phenoxyethanol, Polysorbate-60, Propyl Paraben, Propylene Glycol, Salmon Oil, Sodium Hydroxide, Squalane, Stearyl Alcohol, Stearic Acid, Tetrasodium EDTA, Tocopherol, Tocopheryl Acetate, Vitis Vinifera (Grape) Seed Oil

OPRAVA

methyl salicylate, menthol, capsaicin cream

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:83538-102
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
METHYL SALICYLATE (UNII: LAV5U5022Y) (SALICYLIC ACID - UNII: O414PZ 4LPZ)	METHYL SALICYLATE	10 g in 100 mL	
CAPSAICIN (UNII: S07044R1ZM) (CAPSAICIN - UNII:S07044R1ZM)	CAPSAICIN	0.03 g in 100 mL	
MENTHOL (UNII: L7T10EIP3A) (MENTHOL - UNII:L7T10EIP3A)	MENTHOL	1 g in 100 mL	

Inactive Ingredients		
Ingredient Name	Strength	
PROPYLPARABEN (UNII: Z8IX2SC10H)		
POLYSORBATE 60 (UNII: CAL22UVI4M)		
STEARIC ACID (UNII: 4ELV7Z65AP)		
BORAGE OIL (UNII: F8XAG1755S)		
STEARYL ALCOHOL (UNII: 2KR89I4H1Y)		

EDETATE SODIUM (UNII: MP1J8420LU)	
TOCOPHEROL (UNII: R0ZB2556P8)	
METHYLPARABEN (UNII: A2I8C7HI9T)	
CETYL ALCOHOL (UNII: 936JST6JCN)	
CETOSTEARYL ALCOHOL (UNII: 2DMT128M1S)	
WATER (UNII: 059QF0KO0R)	
EUCALYPTUS OIL (UNII: 2R04ONI662)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
ATLANTIC SALMON OIL (UNII: 15NDG5B709)	
SODIUM HYDROXIDE (UNII: 55X04QC32I)	
OLIVE OIL (UNII: 6UYK2W1W1E)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
SQUALANE (UNII: GW89575KF9)	
FRUCTOSE (UNII: 6YSS42VSEV)	
.ALPHATOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
GRAPE SEED OIL (UNII: 930MLC8XGG)	
CARBOMER HOMOPOLYMER, UNSPECIFIED TYPE (UNII: 0A5MM307FC)	
LAVENDER OIL (UNII: ZBP1YXW0H8)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	

l	Packaging				
	#	Item Code	Package Description	Marketing Start Date	Marketing End Date
	1	NDC:83538-102- 18	237 mL in 1 BOTTLE; Type 0: Not a Combination Product	08/08/2023	

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M017	08/08/2023	

Labeler - Biological M.D. Solutions LLC (118991463)

Revised: 1/2024 Biological M.D. Solutions LLC