# BIOSAVIA EXTERNAL ANALGESIC PAIN RELIEF- capsaicin gel BIOSAVIA USA, LLC

-----

# **BIOSAVIA External Analgesic Pain Relief Gel**

### **Drug Facts**

# Active ingredients

Capsaicin 0.025 %

# Purpose

**Topical Analgesic** 

#### Uses

Temporaryly relieves minor aches and pains of muscles and joints associated with

- strains
- bruises
- sprains
- arthritis
- simple neck or back ache

# Warnings

# For external use only

#### Do not

- use on wounds or damaged skin
- use if you are allergic to any ingredients in this product

# When using this product

Avoid contact with the eyes

# Stop use and ask a doctor if

- symptoms persist or get worse after than 7days
- swallowed

# If pregnant or breast-feeding,

ask a health professional before use

# keep out reach of children

#### **Directions**

Adults and children 2 years of age and older apply liberally onto affected area not more than 3 to 4 times daily

- Massage evenly where needed until the gel is fully absorbed
- Massage your feet for a better sleep
- For a craneal massage, use on your head from your neck to your temples pressing all over your scalp
- massage on afected area for physical fatigue, swollen feet and legs

#### Other information

- Store between 20-25C (68-77 F)
- store in a cool dry place away from direct sun light

# Other Ingredients

Aloe Barbadensis Leaf Juice, Arnica Montana Extract, Carbomer, Citrus Aurantium Dulcis (Orange) Peel Oil, DMDM Hydantoin, Glycerin, Isopropyl Myristate, Mentha Piperita (Peppermint) Oil, Mineral Oil, Panax Ginseng Root Extract, PEG-12 Dimethicone, PEG-40 Hydrogenated Castor Oil, Red 40 (CI 16035), Sodium Hydroxide, Tetrasodium EDTA, Water (Aqua)

Questions?

(954) 588-9852

**Package Labeling:** 

# **Penetrating Pain Relief** BIOSAVI

**External Analgesic Gel Full Body Massage** 



- + Fast soothe for cramps and bumps
- + Support tiredness
- + Ideal for sports
- + Effective Action
- + Cool Sensation

Net weight 4 oz / 117.5 g



# Drug Facts

Active ingredients Capsaicin 0.025 %

Purpose

Topical Analgesic

**Uses** Temporaryly relieves minor aches and pains of muscles and joints associated with ■ strains ■ bruises ■ sprains ■ arthritis ■ simple neck or back ache

#### Warnings

For external use only

Do not ■ use on wounds or damaged skin ■ use if you are allergic to any ingredients in this product When using this product ■ Avoid contact with the eyes Stop use and ask a doctor if ■ symptoms persist or get worse after than 7days ■ swallowed

If pregnant or breast-feeding, ask a health professional before use ■ keep out reach of children

#### **Directions**

Adults and children 2 years of age and older apply liberally onto affected area not more than 3 to 4 times daily Massage evenly where needed until the gel is fully absorbed Massage your feet for a better sleep For a craneal massage, use on your head from your neck to your temples pressing all over your scalp ■ massage on afected area for physical fatigue, swollen feet and legs

#### Other information

■ Store between 20-25C (68-77 F) ■ store in a cool dry place away from direct sun light

#### Other Ingredients

Aloe Barbadensis Leaf Juice, Arnica Montana Extract, Carbomer, Citrus Aurantium Dulcis (Orange) Peel Oil, DMDM Hydantoin, Glycerin, Isopropyl Myristate, Mentha Piperita (Peppermint) Oil, Mineral Oil, Panax Ginseng Root Extract, PEG-12 Dimethicone, PEG-40 Hydrogenated Castor Oil, Red 40 (Cl 16035), Sodium Hydroxide, Tetrasodium EDTA, Water (Aqua)

Questions? (954) 588-9852

# BIOSAVIA

Distributed by: BIOSAVIA USA LLC Miami - Florida 33132 United States www.biosavia.com

# **BIOSAVIA EXTERNAL ANALGESIC PAIN RELIEF**

capsaicin gel

<b>Product</b>	Intorm	ation

**Product Type** HUMAN OTC DRUG Item Code (Source) NDC:84680-529

**Route of Administration TOPICAL** 

Active Ingredient/Active Moiety			
Ingredient Name	<b>Basis of Strength</b>	Strength	
CAPSAICIN (UNII: S07044R1ZM) (CAPSAICIN - UNII:S07044R1ZM)	CAPSAICIN	0.25 mg in 1 g	

Inactive Ingredients		
Ingredient Name	Strength	
ALOE VERA LEAF (UNII: ZY81Z83H0X)		
ARNICA MONTANA WHOLE (UNII: O80TY208ZW)		
CARBOMER HOMOPOLYMER, UNSPECIFIED TYPE (UNII: 0A5MM307FC)		
ORANGE OIL, COLD PRESSED (UNII: AKN3KSD11B)		
DMDM HYDANTOIN (UNII: BYR0546TOW)		
GLYCERIN (UNII: PDC6A3C0OX)		
ISOPROPYL MYRISTATE (UNII: ORE8K4LNJS)		
PEPPERMINT OIL (UNII: AV092KU4JH)		
MINERAL OIL (UNII: T5L8T28FGP)		
ASIAN GINSENG (UNII: CUQ3A77YXI)		
PEG-12 DIMETHICONE (UNII: ZEL54N6W95)		
POLYOXYL 40 HYDROGENATED CASTOR OIL (UNII: 7YC686GQ8F)		
FD&C RED NO. 40 (UNII: WZB9127XOA)		
SODIUM HYDROXIDE (UNII: 55X04QC32I)		
EDETATE SODIUM (UNII: MP1J8420LU)		
WATER (UNII: 059QF0KO0R)		

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
		117.5 g in 1 BOTTLE; Type 0: Not a Combination Product	08/19/2024	

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M017	08/19/2024	

# Labeler - BIOSAVIA USA, LLC (119326193)

Revised: 8/2024 BIOSAVIA USA, LLC