

PAINZONE- external analgesic cream

MedZone Products LLC

Disclaimer: Most OTC drugs are not reviewed and approved by FDA, however they may be marketed if they comply with applicable regulations and policies. FDA has not evaluated whether this product complies.

PainZone

Active Ingredients

Camphor 3%

Menthol 12%

Methyl Salicylate 20%

Purpose

Analgesic

Counterirritant

Counterirritant

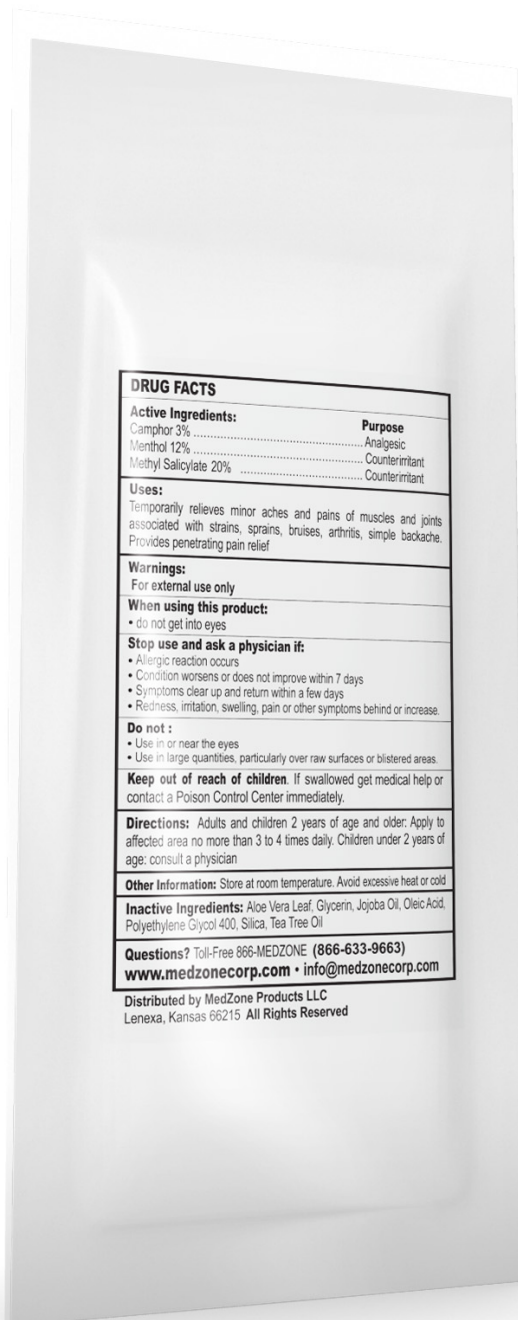
Uses

Temporarily relieves minor aches and pains of muscle and joints associated with strains, sprains, arthritis, simple backache.

Provides penetrating pain relief.

Warnings

For external use only.

**DRUG FACTS**

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Warnings:
For external use only

When using this product:
• do not get into eyes

Stop use and ask a physician if:
• Allergic reaction occurs
• Condition worsens or does not improve within 7 days
• Symptoms clear up and return within a few days
• Redness, irritation, swelling, pain or other symptoms behind or increase.

Do not:
• Use in or near the eyes
• Use in large quantities, particularly over raw surfaces or blistered areas.

Keep out of reach of children. If swallowed get medical help or contact a Poison Control Center immediately.

Directions: Adults and children 2 years of age and older: Apply to affected area no more than 3 to 4 times daily. Children under 2 years of age: consult a physician

Other Information: Store at room temperature. Avoid excessive heat or cold

Inactive Ingredients: Aloe Vera Leaf, Glycerin, Jojoba Oil, Oleic Acid, Polyethylene Glycol 400, Silica, Tea Tree Oil

Questions? Toll-Free 866-MEDZONE (866-633-9663)
www.medzonecorp.com • info@medzonecorp.com

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Lenexa, Kansas 66215 All Rights Reserved

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MedZone
SINCE 2001

PainZone
Penetrating Pain Relief

CREATED BY
SPORTS MEDICAL PROFESSIONALS

Helps With:

- Sore Muscles & Joints
- Arthritis Symptoms
- Muscle Strain
- Eases Back Pain
- Deep Penetrating Relief
- Sprains

MADE IN USA

3 fl oz. / 88ml
NDC# 70338-641-30

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DRUG FACTS		Stop use and ask a physician if: Allergic reaction occurs / Condition worsens or does not improve within 7 days / Symptoms begin or increase / Redness, irritation, swelling, pain or other symptoms begin or increase.	Children under 2 years of age: consult a physician. Shake well before using
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Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:70338-641
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
CAMPHOR, (-)- (UNII: 213N3S8275) (CAMPHOR, (-)- - UNII:213N3S8275)	CAMPHOR, (-)-	30 mg in 1 g
MENTHOL (UNII: L7T10EIP3A) (MENTHOL - UNII:L7T10EIP3A)	MENTHOL	120 mg in 1 g
METHYL SALICYLATE (UNII: LAV5U5022Y) (SALICYLIC ACID - UNII:O414PZ4LPZ)	METHYL SALICYLATE	200 mg in 1 g

Inactive Ingredients

Ingredient Name	Strength
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
GLYCERIN (UNII: PDC6A3C0OX)	
JOJOBA OIL (UNII: 724GKU717M)	
OLEIC ACID (UNII: 2UMI9U37CP)	
POLYETHYLENE GLYCOL 400 (UNII: B697894SGQ)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
TEA TREE OIL (UNII: VIF565UC2G)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
	NDC:70338-641			

1	NDC:70338-641-12	3.6 g in 1 POUCH; Type 0: Not a Combination Product	07/01/2016	
2	NDC:70338-641-30	88 g in 1 BOTTLE, WITH APPLICATOR; Type 0: Not a Combination Product	09/30/2016	
3	NDC:70338-641-10	28 g in 1 BOTTLE, WITH APPLICATOR; Type 0: Not a Combination Product	09/30/2016	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part348	07/01/2016	

Labeler - MedZone Products LLC (080083739)

Registrant - Richard Hamer Associates LLC (067731889)

Establishment

Name	Address	ID/FEI	Business Operations
Biomed Laboratories LLC		055329696	pack(70338-641) , manufacture(70338-641)

Establishment

Name	Address	ID/FEI	Business Operations
Micro Consult Inc		062183608	analysis(70338-641)

Establishment

Name	Address	ID/FEI	Business Operations
Ceutical Laboratories Inc		789485153	analysis(70338-641)

Revised: 2/2018

MedZone Products LLC