

PAINAZIN CP- capsaicin spray
Concept Laboratories, Inc.

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.

PAINAZIN-CP THERAPEUTIC PAIN RELIEVING SPRAY

Drug Facts

Active ingredient

Capsicum Oleoresin 0.0625% (Containing Capsaicin 0.025%)

Purpose

Pain Relieving

Uses

for the temporary relief of minor aches and pains of muscles and joints associated with

- simple backache
- arthritis
- strains
- sprains
- bruises

Warnings

For external use only.

- do not apply to wounds or damaged skin
- do not bandage tightly
- do not use with heating pad, pack, wrap, hot water bottle or any heating element

When using this product do not get into eyes

- avoid contact with other mucous membranes

Discontinue use and ask a doctor if condition worsens or if symptoms persist for more than 7 days or 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 nursing**, seek the advice of a health professional before using

Directions

- Children under 12 years of age consult a physician
- To avoid inhaling product, hold bottle close to skin while spraying
- Apply a thin layer to affected area not more than 3 to 4 times daily
- Gently massage into the skin until fully absorbed
- Wash hands with soap and water after each application to avoid spreading to the eyes or other sensitive mucous membranes

Other information

- It is recommended to test for skin sensitivity prior to use. Apply product to a small area, follow the directions and wait 24 hours. Proceed with application if no adverse reaction.
- A burning sensation may occur upon initial application but generally disappears with continued use. For a severe burning discomfort, remove excess product with a soft cloth and cooking oil.
- If applying product to hands, wait 30 minutes before washing.
- Avoid water, heat, or direct sunlight while using product.
- If wearing contact lenses, insert prior to application and avoid touching them after applying product.
- If eye contact occurs, flush immediately with water.

Inactive ingredients

Water (Aqua), Glycerin, PEG-75 Lanolin, Aloe Barbadensis Leaf Juice, PEG-40 Hydrogenated Castor Oil, Carbomer, Triethanolamine, Glucosamine HCl, Medicago Sativa (Alfalfa) Extract, Ginkgo Biloba Leaf Extract, Cymbopogon Schoenanthus Extract, Seed of Celosia Argentea Extract, Dimethyl Sulfone, Panax Ginseng Root Extract, Polysorbate 20, Tocopheryl Acetate, Emu Oil, Propylene Glycol, DMDM Hydantoin, Methylparaben, Propylparaben.

Questions or comments?

Call 1-888-373-8831 or visit www.conceptlabs.org

PRINCIPAL DISPLAY PANEL - 118mL Bottle Label

NDC 64058-117-14

Painazin-CP™**Therapeutic****Pain Relieving Spray**

with Emu Oil, Glucosamine & MSM

Penetrating Pain Relief

- Arthritis
- Simple Backache
- Strains
- Sprains

Greaseless • Odorless • Stainless

4 FL OZ (118mL)

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Warnings

For external use only. ■ do not apply to wounds or damaged skin.

When using this product avoid contact with the eyes

Stop use and ask a doctor if condition worsens

Keep out of reach of children.

Directions

■ Apply a thin layer to affected area not more than 3 to 4 times daily

Other information

See outer bag label for complete Directions and Warnings before using.

Inactive ingredients Water (Aqua), Glycerin, PEG-75 Lanolin, Aloe Barbadensis Leaf Juice, PEG-40 Hydrogenated Castor Oil, Carbomer, Triethanolamine, Glucosamine HCl, Medicago Sativa (Alfalfa) Extract, Ginkgo Biloba Leaf Extract, Cymbopogon Schoenanthus Extract, Seed of Celosia Argentea Extract, Dimethyl Sulfone, Panax Ginseng Root Extract, Polysorbate 20, Tocopheryl Acetate, Emu Oil, Propylene Glycol, DMDM Hydantoin, Methylparaben, Propylparaben.

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Manufactured by:
Concept Laboratories, Inc.
Chicago, IL 60642
Made in USA

#CL9888 R1

PAINAZIN CP

capsaicin spray

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:64058-117
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
Capsaicin (UNII: S07O44R1ZM) (Capsaicin - UNII:S07O44R1ZM)	Capsaicin	0.00025 g in 1 mL

Inactive Ingredients

Ingredient Name	Strength
Water (UNII: 059QF0KO0R)	
GLYCERIN (UNII: PDC6A3C0OX)	
DIMETHYL SULFONE (UNII: 9H4PO4Z4FT)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
MEDICAGO SATIVA LEAF (UNII: HY3L927V6M)	
CYMBOPOGON SCHOENANTHUS LEAF (UNII: XF54B1Z2HF)	
GLUCOSAMINE HYDROCHLORIDE (UNII: 750W5330FY)	
GINKGO (UNII: 19FUJ2C58T)	

POLYSORBATE 20 (UNII: 7T1F30V5YH)	
EMU OIL (UNII: 344821WD61)	
DMDM HYDANTOIN (UNII: BYR0546TOW)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
METHYLPARABEN (UNII: A2I8C7HI9T)	
PROPYLPARABEN (UNII: Z8IX2SC1OH)	

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:64058-117-14	118 mL in 1 BOTTLE		

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part348	01/27/2011	

Labeler - Concept Laboratories, Inc. (962282612)

Establishment			
Name	Address	ID/FEI	Business Operations
Concept Laboratories, Inc.		962282612	MANUFACTURE

Revised: 7/2011

Concept Laboratories, Inc.