

SHERMAN AND CLARK PAIN RELIEVING- capsaicin gel
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.

SHERMAN & CLARK PAIN RELIEVING LINIMENT

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 n simple backache n arthritis n strains n sprains n bruises

Warnings

For external use only.

Do not apply to wounds or damaged skin. Do not bandage tightly. Do not use with heating pad, 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

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, Acrylates/C10-30 Alkyl Acrylate Crosspolymer, Triethanolamine, Polysorbate 20, Glucosamine HCl, Emu Oil, Dimethyl Sulfone, Celosia Argentea Seed Extract, Ginkgo Biloba Extract, Panax Ginseng Root Extract, Medicago Sativa (Alfalfa) Extract, Cymbopogon Schoenanthus Extract, Tocopheryl Acetate, DMDM Hydantoin, Propylene Glycol, Methylparaben, Propylparaben.

Questions or comments?

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

Manufactured by Concept Laboratories, Inc., Chicago, IL 60642
#BG-#SC0003

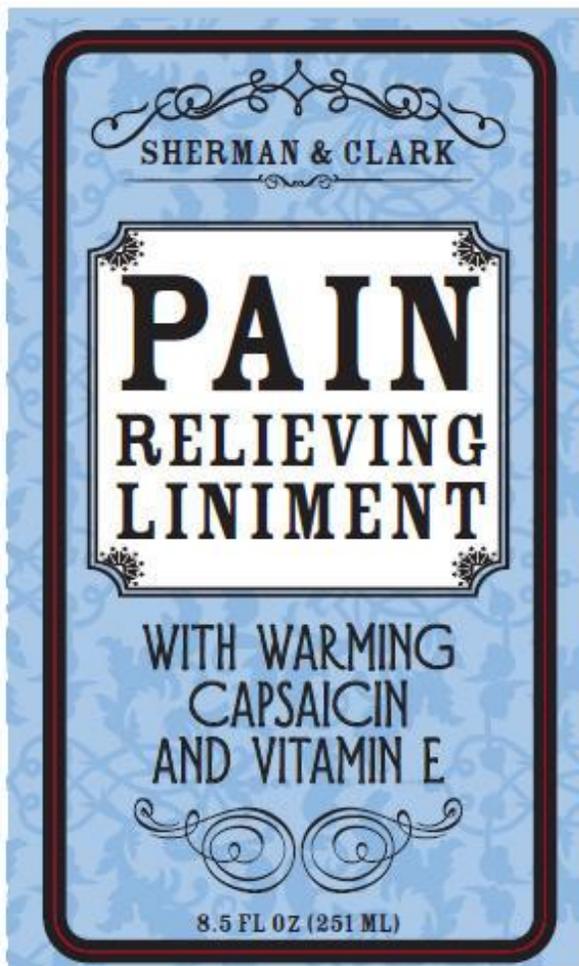
PRINCIPAL DISPLAY PANEL - 251 ML Bottle Label

Sherman & Clark

**PAIN
RELIEVING
LINIMENT**

WITH WARMING
CAPSAICIN
AND VITAMIN E

8.5 FL OZ (251 ML)



Drug Facts

Active Ingredient	Purpose
Capsicum Oleoresin 0.0625% (Containing Capsaicin 0.025%)	Pain Relieving

Uses for the temporary relief of minor aches and pains of muscles and joints associated with
 ■ simple backache ■ arthritis ■ strains

Warnings

For external use only. ■ do not apply to wounds or damaged skin ■ do not bandage tightly ■ do not use with heating pad, 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.

See Drug Facts label on outer packaging for complete Uses, Warnings and Directions.

Directions

■ 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

Inactive Ingredients

See Drug Facts label on outer packaging

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Chicago, IL 60642 www.conceptlabs.org

NDC 64058-613-18

#SC0003

SHERMAN AND CLARK PAIN RELIEVING

capsaicin gel

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:64058-613
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
Capsaicin (UNII: S07O44R1ZM) (Capsaicin - UNII:S07O44R1ZM)	Capsaicin	0.06275 g in 251 mL

Inactive Ingredients

Ingredient Name	Strength
Water (UNII: 059QF0KO0R)	
Glycerin (UNII: PDC6A3C0OX)	
PEG-75 LANOLIN (UNII: 09179OX7TB)	
DIMETHYL SULFONE (UNII: 9H4PO4Z4FT)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
MEDICAGO SATIVA LEAF (UNII: HY3L927V6M)	
CYMOPOGON 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:64058-613-18	251 mL in 1 BOTTLE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH FINAL	part348	12/06/2011	

Labeler - Concept Laboratories, Inc. (962282612)

Establishment

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

Revised: 10/2011

Concept Laboratories, Inc.