

SHEFFIELD ARTHRITIS AND MUSCLE PAIN RELIEF- capsicum oleoresin cream
Sheffield Pharmaceuticals 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.

Drug Facts

Active Ingredient

Capsicum Oleoresin 0.025%

Purpose

<Topical analgesic>

Uses

- For the temporary relief of minor aches and pains of muscles and joints associated with simple backache, arthritis, strains, bruises and sprains

Warnings

For external use only

Avoid contact with the eyes and mucous membranes

- If condition worsens, or if symptoms persist for more than 7 days or clear up and occur again within a few days, discontinue use of this product and consult a doctor.
- Do not apply to wounds or damaged skin.
- Do not bandage tightly.
- Do not use with a heating pad or on wounds, damaged, broken (open) or irritated skin.
- Discontinue use if excessive irritation of skin develops.
- If pregnant or breast feeding, ask a health professional before use.
- A temporary burning sensation may occur upon application, but generally disappears in a few days

Keep this and all drugs out of the 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 the affected area not more than 3 to 4 times daily. Children under 2 years of age: consult a doctor.
- Unless treating hands, wash thoroughly with soap and water immediately after use.

Inactive ingredients

Benzyl Alcohol, Cetyl Alcohol, Glyceryl Sterate, Isopropyl Myristate, Paraffin, PEG-100 Stearate, Petrolatum, Purified Water, Sorbitol

Other Information

- Store at controlled room temperature 20°- 25°C (68° - 77°F)
- Close the cap tightly after use

Principal Display Panel – 1.5oz Carton Label

Dr. Sheffield's

NDC 11527-089-54

SHEAF-FIELD TM

Made in the USA

ARTHRITIS & MUSCLE PAIN RELIEF CREAM

Topical Analgesic

NET WT. 1.5 oz. (43g)



Dr. Sheffield's
Made in the USA

**ARTHRITIS & MUSCLE
PAIN RELIEF CREAM**

Drug Facts	Purpose
Active ingredient Capsicum oleoresin (Capsaicin 0.025%)	Topical analgesic
Uses For the temporary relief of minor aches and pains of muscles and joints associated with simple backache, arthritis, strains, bruises and sprains.	
Warnings <u>For external use only</u> Avoid contact with the eyes and mucous membranes.	
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**Dr. Sheffield's
ARTHRITIS & MUSCLE
PAIN RELIEF CREAM**





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Dr. Sheffield's
ARTHRITIS & MUSCLE
PAIN RELIEF CREAM

Compare to the active ingredients of ZOSTRIX®



Effective Relief of Arthritis & Muscle Pain
Topical Analgesic
Original Strength Capsicum Oleoresin (Capsaicin 0.025%)

Dr. Sheffield's
THERMA-RUB
MADE IN THE USA



Effective Relief of Arthritis & Muscle Pain
Topical Analgesic
NET WT. 1.5 oz. (43g)

For Relief of Arthritis & Muscle Pain
Effective Strength Capsicum Oleoresin (Capsaicin)

NDC 11527-089-54

**ARTHRITIS & MUSCLE
PAIN RELIEF CREAM**

Topical Analgesic
NET WT. 1.5 oz. (43g)

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For Relief of Arthritis & Muscle Pain
Effective Strength Capsicum Oleoresin (Capsaicin)

NDC 11527-089-54

**ARTHRITIS & MUSCLE
PAIN RELIEF CREAM**

Topical Analgesic
NET WT. 1.5 oz. (43g)

Dr. Sheffield's
ARTHRITIS & MUSCLE
PAIN RELIEF CREAM

Principal Display Panel – 1.5oz Tube Label

Dr. Sheffield's NDC 11527-089-54

SHEAF-FIELD TM

Made in the USA

ARTHRITIS & MUSCLE PAIN RELIEF CREAM

Topical Analgesic

NET WT. 1.5 oz. (43g)

Dr. Sheffield's THERMA-RUB™ NDC 11527-089-54

ARTHHRITIS & MUSCLE PAIN RELIEF CREAM

Made in the USA Topical Analgesic NET WT. 1.5 oz. (43g)

Active ingredient: Capsicum oleoresin (Capsaicin 0.025%) *Purpose:* Topical analgesic
Uses: For the temporary relief of minor aches and pains of muscles and joints associated with simple backache, arthritis, strains, bruises and sprains.
Warnings: For external use only. Avoid contact with the eyes and mucous membranes. ■ If condition worsens, or if symptoms persist for more than 7 days or clear up and occur again within a few days, discontinue use of this product and consult a doctor. ■ Do not apply to wounds or damaged skin. ■ Do not bandage tightly. ■ Do not use with a heating pad or on wounds, damaged, broken (open) or irritated skin. ■ Discontinue use if excessive irritation of skin develops. ■ If pregnant or breast feeding, ask a health professional before use. ■ A temporary burning sensation may occur upon application, but generally disappears in a few days.
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Other information: Store at controlled room temperature 20°- 25°C (68°- 77°F) ■ Close the cap tightly after use.
SHEFFIELD PHARMACEUTICALS www.sheffield-pharmaceuticals.com New London, CT 06320 USA *Questions?* 1-800-222-1087 Made in the USA

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SHEFFIELD ARTHRITIS AND MUSCLE PAIN RELIEF

capsicum oleoresin cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:11527-089
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
CAPSICUM OLEORESIN (UNII: UW86K581WY) (CAPSICUM OLEORESIN - UNII:UW86K581WY)	CAPSICUM	0.25 mg in 1 g

Inactive Ingredients

Ingredient Name	Strength
SORBITOL (UNII: 506T60A25R)	
WATER (UNII: 059QF0KO0R)	
ISOPROPYL MYRISTATE (UNII: 0RE8K4LNJS)	
CETYL ALCOHOL (UNII: 936JST6JCN)	
GLYCERYL MONOSTEARATE (UNII: 230OU9XXE4)	
PEG-100 STEARATE (UNII: YD01N1999R)	
BENZYL ALCOHOL (UNII: LKG8494WBH)	
PETROLATUM (UNII: 4T6H12BN9U)	
PARAFFIN (UNII: I9O0E3H2ZE)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:11527-089-54	1 in 1 CARTON	04/14/2010	
1		43 g in 1 TUBE; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part348	04/14/2010	

Labeler - Sheffield Pharmaceuticals LLC (151177797)

Establishment

Name	Address	ID/FEI	Business Operations
Sheffield Pharmaceuticals LLC		151177797	MANUFACTURE(11527-089)

Revised: 12/2019

Sheffield Pharmaceuticals LLC