

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

Sheffield Thermarub Capsaicin Cream

Drug Facts

Active Ingredient

Capsicum Oleoresin 0.075%

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 - 60gm Carton Label

Sheffield Pharmaceuticals

NDC 11527-080-60

High Potency

ARTHRITIS & MUSCLE PAIN RELIEF CREAM

0.075% Capsaicin Topical Analgesic Cream

NET WT. 60g (2.11oz)



Principal Display Panel - 60g Tube Label

Sheffield Pharmaceuticals

NDC 11527-080-60

High Potency

ARTHRITIS & MUSCLE PAIN RELIEF CREAM

0.075% Capsaicin Topical Analgesic Cream

NET WT. 60g (2.11oz)



NDC 11527-080-60

High Potency

Arthritis & Muscle Pain Relief Cream

ThermaRub™ 0.075% Capsaicin Topical Analgesic Cream
For Temporary Relief of • Arthritis Pain • Muscle Pain

NET WT. 60g (2.11 OZ)



Active ingredient: Capsicum oleoresin (Capsicum 0.075%).....**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 affected area not more than 3 to 4 times daily. **Children under 2 years of age:** consult a doctor. • Unless treating hands, wash hands thoroughly with soap and water immediately after use. **Other Information:** Store at controlled room temperature 20° - 25°C (68°- 77°F) • Close the cap tightly after use. **Questions? 1-800-222-1087**

Distributed by: Sheffield Pharmaceuticals, 170 Broad Street, New London, CT 06320 www.sheffieldpharma.com

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2501921



NDC 11527-080-60

High Potency

Arthritis & Muscle Pain Relief Cream

ThermaRub™ 0.075% Capsaicin Topical Analgesic Cream
For Temporary Relief of • Arthritis Pain • Muscle Pain

NET WT. 60g (2.11 OZ)



Active ingredient: Capsicum oleoresin (Capsicum 0.075%).....**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 affected area not more than 3 to 4 times daily. **Children under 2 years of age:** consult a doctor. • Unless treating hands, wash hands thoroughly with soap and water immediately after use. **Other Information:** Store at controlled room temperature 20° - 25°C (68°- 77°F) • Close the cap tightly after use. **Questions? 1-800-222-1087**

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SHEFFIELD ARTHRITIS AND MUSCLE PAIN RELIEF

capsicum oleoresin cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:11527-080
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
CAPSICUM OLEORESIN (UNII: UW86K581WY) (CAPSICUM OLEORESIN - UNII:UW86K581WY)	CAPSAICIN	.075 g in 100 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:11527-080-60	1 in 1 CARTON	12/22/2020	
1		60 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 Drug	M017	12/22/2020	

Labeler - Sheffield Pharmaceuticals LLC (151177797)

Establishment

Name	Address	ID/FEI	Business Operations
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Sheffield Pharmaceuticals LLC		151177797	MANUFACTURE(11527-080) , analysis(11527-080)
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Revised: 11/2023

Sheffield Pharmaceuticals LLC