

CAMPO PHARMA MUSCLE HOT- capsaicin cream
Latin Shots, 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.

Campo pharma Muscle hot

Drug Facts

Active Ingredients

Capsaicin 0.050%

Purpose

Counterirritant

Uses:

For the temporary relief of minor aches and pains of muscles and joints associated with strains, sprains, tendonitis, simple backache, and arthritis, combined with stretching and calisthenics, Red Hot assists in the warm-up process, especially in cool, damp weather.

Warnings:

External use only

- In case of accidental ingestion, seek professional assistance or contact a Poison Control Center immediately. Use only as directed. If condition worsens, or if the symptoms persist for more than 7 days, or clear up and occur again within few days, discontinue use, and consult a doctor.

Keep this and oil drugs out of the reach of children.

Directions:

- This product is a strong counterirritant. Apply sparingly. Adults and children 6 years of age older: apply to affected area no more than 3-4 times daily. Children under 6 years of age: consult a doctor.

Other information:

This product is intended to and will cause mild skin irritation. Discontinue use if excessive irritation of skin develops. Avoid getting into eyes or on mucous membranes. Do not apply to irritated or broken skin, Store in a cool, dry place with lid closed tightly.

Inactive ingredient:

Mineral Oil, Paraffin, Petrolatum

Package Labeling:

CAMPO PHARMA
PRODUCTS

MUSCLE HOT

TEMPORARY RELIEF OF MUSCLE DISABILITIES

Relieves Minor Pain of Strains and Sprains
Relaxes Tight, Aching Muscles
Assists in Warm-up

FOR EXTERNAL USE
Peso Neto: 14 oz (397 gramos)

Drug Facts

Active Ingredients	Purpose
Capsaicin 0.050%	Counterirritant

Uses:

- For the temporary relief of minor aches and pains of muscles and joints associated with strains, sprains, tendonitis, simple backache and arthritis, combined with soothing and calisthenics, Heat Hot assists in the warm-up process, especially in cool, damp weather.

Warnings:

External use only

- In case of accidental ingestion, seek professional assistance or contact a Poison Control Center immediately. Use only as directed. If condition worsens, or if the temporary relief is not had for 7 days, or if the pain or other signs which may accompany use, discontinue use, and consult a doctor. Keep this and all drugs out of the reach of children.

Directions:

- This product is a strong counterirritant. Apply sparingly. Adults and children 6 years of age and older: apply to affected area not more than 3 - 4 times daily. Children under 6 years of age: consult a doctor.

Other information:

- This product is intended to soothe and will cause mild skin irritation. Discontinue use if excessive irritation of skin develops. Avoid getting into eyes or on mucous membranes. Do not apply to inflamed or broken skin. Store in a cool, dry place with lid closed tightly.

Inactive Ingredient: Mineral Oil, Paraffin, Petrolatum

MANUFACTURED BY CAMPO PHARMA PRODUCTS
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CAMPO PHARMA MUSCLE HOT

capsaicin cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:82777-001
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
CAPSAICIN (UNII: S07O44R1ZM) (CAPSAICIN - UNII:S07O44R1ZM)	CAPSAICIN	0.5 mg in 1 g

Inactive Ingredients

Ingredient Name	Strength
MINERAL OIL (UNII: T5L8T28FGP)	
PARAFFIN (UNII: I9O0E3H2ZE)	
PETROLATUM (UNII: 4T6H12BN9U)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:82777-001-01	397 g in 1 JAR; Type 0: Not a Combination Product	09/01/2022	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part348	09/01/2022	

Labeler - Latin Shots, Inc (080681098)

Revised: 1/2023

Latin Shots, Inc