

RED HOT- capsaicin ointment
Performance Health, 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.

Red Hot Ointment

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

For 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 a few days, discontinue use and consult a doctor.

Keep this and all drugs out of 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 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 Ingredients

Mineral Oil, Paraffin, Petrolatum

Questions?

(800) 345-2231

Package Labeling:



HOT
TOPICAL
ANALGESIC
OINTMENT

RED HOT OINTMENT®

World Leader in Sports Medicine Since 1918™

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

NET WT 1 Lb (454 g)



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Questions? (800) 345-2231	Made in the U.S.A.
Stock No, 180538 P08492 Rev 1 NDC 59316-996-96	Performance Health, LLC, Akron, Ohio 44310

RED HOT

capsaicin ointment

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:59316-996
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
CAPSAICIN (UNII: S07O44R1Z M) (CAPSAICIN - UNII:S07O44R1Z M)	CAPSAICIN	0.05 g in 100 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:59316-996-21	78 g in 1 TUBE; Type 0: Not a Combination Product	05/19/2017	12/31/2024
2	NDC:59316-996-96	454 g in 1 BOTTLE; Type 0: Not a Combination Product	05/19/2017	12/31/2024

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part348	05/19/2017	12/31/2024

Labeler - Performance Health, LLC (794324061)

Revised: 8/2022

Performance Health, LLC