ZOSTRIX FOOT PAIN RELIEF- capsaicin cream Health Care Products

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

Capsaicin 0.075%

Purpose

Topical Analgesic

Uses

For the temporary relief of minor aches and pains of the muscle joints associated with

- strains
- sprains
- bruises
- arthritis

Warnings

For external use only.

Do not apply to wounds or to damaged or irritated skin.

When using this product

- you may experience a burning sensation which is normal and related to the way the product works. With regular use, this sensation generally disappears within several days.
- Avoid contact with eyes. Do not get it on mucous membranes, into eyes, or on contact lenses. If this occurs, rinse the affected area thoroughly with water.
- do not apply immediately before or after activities such as bathing, swimming, sun bathing, or strenuous exercise
- do not apply heat to the treated areas immediately before or after use
- do not tightly wrap or bandage the treated area
- avoid inhaling airborne material from dried residue. This can result in coughing, sneezing, tearing, throat or respiratory irritation.

Stop 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
- blistering occurs
- difficulty breathing or swallowing occurs
- severe burning persists

Keep out of reach of children.

If swallowed, get medical help or contact a Poison Control Center immediately.

Directions

- for persons under 18 years of age, ask a doctor before using
- to avoid getting cream on hands use applicator pad to apply a thin film of cream to the affected area and gently rub in until fully absorbed. Discard applicator pad after use.
- for optimum relief, apply 3 to 4 times daily
- best results typically occur after 2 to 4 weeks of continuous use
- unless treating hands, wash hands thoroughly with soap and water immediately after use
- see package insert for more information

Other information

Store at 15°-30°C (59°-86°F).

Inactive ingredients

Benzyl Alcohol, Cetyl Alcohol, Glyceryl Stearate, Isopropyl Myristate, PEG-100 Stearate, Purified Water, Sorbitol Solution & White Petrolatum.

Questions or Comments?

Call: **1-800-899-3116**, Mon. - Thurs. 9:00 am - 5:00 pm EST, Fri. 9:00 am - 2:30 pm EST. Serious side effects associated with the use of this product may be reported to this number.

Rev. 188:01 3/11

Package/Label Principal Display Panel

IMPORTANT:
Pollow the enclosed directions. Zostrix works best by using a <u>smail</u> amount of cream (the size of a pea) each time you apply it. Apply 3-4 times daily.



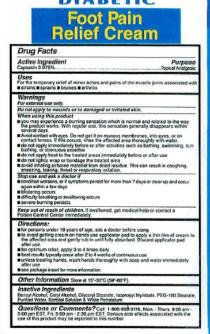
ZOSTRIX

Foot Pain Relief Cream

For Relief of Diabetic Foot Pain

Clinically tested pain relief without a prescription
Provides powerful penetrating relief
Odorless
APPLICATION FOR PAIN TO CARD HOLES APPLICATION FOR THE TOMAL ANALISSIC CREAM Capulcia 0.075%. Net Wi. 202.156.6g)

ZOSTRIX





Zostrix[®] – The brand for pain relief

- · Clinically tested
- Strong, effective and odorless

Zostrix® Diabetic Foot Pain Relief Cream is a powerful medication containing the strength of purified capsaicin, the natural active component of chili peppers.

Manufactured for:

Top
Health Care Products
a division of M-Tech Pharmacal Co., Inc.
Amilyville, NY 11701





Foot Pain Relief Cream

For Relief Of Diabetic Foot Pain

- Clinically tested pain relief without a prescription
- Provides powerful penetrating relief
- ◆ Odorless

◆ Greaseless

Capsaicin 0.075% Net Wt. 2 oz. (56.6g) INGLUDES
APPLICATOR PADS
to keep hands medication free
TOPICAL ANALGESIC CREAM

Rev # 188:01 3/11 Style # 188-02-05



NDC 61787-188-02

ZOSTRIX[®]

DIABETIC

FOOT PAIN RELIEF CREAM

For Relief of Diabetic Foot Pain

- Clinically tested pain relief without a prescription
- Provides powerful penetrating relief
- Odorless
- Greaseless

Capsaicin 0.075%

Net Wt. 2 oz. (56.6 g)

TOPICAL ANALGESIC CREAM

ZOSTRIX FOOT PAIN RELIEF

capsaicin cream

Product Information

 Product Type
 HUMAN OTC DRUG LABEL
 Item Code (Source)
 NDC:61787-188

Route of Administration TOPICAL DEA Schedule

Active Ingredient/Active Moiety

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Ingredient Name	Basis of Strength	Strength
CAPSAICIN (CAPSAICIN)	CAPSAICIN	0.75 mg in 1 g

Inactive Ingredients

mactive ingredients		
Ingredient Name	Strength	
ISOPROPYL MYRISTATE		
WATER		
SORBITOL		
CETYL ALCOHOL		
PETROLATUM		
GLYCERYL MONOSTEARATE		
PEG-100 STEARATE		
BENZYL ALCOHOL		

Packaging

	- ucing-ing				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date	
1	NDC:61787-188-02	1 in 1 CARTON			
1		56.6 g in 1 TUBE			

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part348	10/01/2009	03/31/2016

Labeler - Health Care Products (101196749)

Registrant - Hi-Tech Pharmacal Co., Inc. (101196749)

Establishment

Name	Address	ID/FEI	Business Operations
Process Technologies & Packaging, LLC		809172885	MANUFACTURE(61787-188)

Revised: 11/2013 Health Care Products