ZOSTRIX HIGH POTENCY FOOT PAIN RELIEF- capsaicin cream
MEDTECH PRODUCTS 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.

Zostrix HP Foot Pain Relief 61787-556

Drug Facts

Active ingredient

Total capsaicin 0.1%

Purpose

Topical Analgesic

Uses

For the temporary relief of minor aches and pains of the muscles and 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 diminishes.
- **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.
- apply a thin film of cream to the affected area and gently rub in until fully absorbed.
- for optimum relief, apply 3 to 4 times daily
- best results typically occur after 2 to 4 weeks of continuous use.
- **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, citric acid*, glyceryl stearate, isopropyl myristate, PEG-100 stearate, purified water, sorbitol solution & white petrolatum. *May contain this ingredient to adjust pH.

Questions or Comments?

Call: **1-800-579-8327**

Serious side effects associated with the use of this product may be reported to this number.

Zostrix.com

Package/Label Principal Display Panel

MAXIMUM STRENGTH

ZOSTRIX®

NATURAL FOOT PAIN RELIEF

Capsaicin 0.1% Topical Anagesic

BLOCKS YOUR BODY’S PAIN MESSENGER

- ODOR FREE CREAM

- WARMTH FROM CHILI PEPPERS

Net Wt. 2 oz. (57 g)

ZOSTRIX HIGH POTENCY FOOT PAIN RELIEF

capsaicin cream

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:61787-556
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
CAPSAICIN (UNII: S07O44R1ZM) (CAPSAICIN - UNII:S07O44R1ZM)	CAPSAICIN	0.75 mg in 1 g

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

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:61787-556-02	1 in 1 CARTON	10/22/2013	
1		56.6 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	10/22/2013	

Labeler - MEDTECH PRODUCTS INC (114707784)

Establishment

Name	Address	ID/FEI	Business Operations
Denison Pharmaceuticals, LLC		001207208	manufacture(61787-556)

Revised: 3/2022 MEDTECH PRODUCTS INC