ZOSTRIX ORIGINAL STRENGTH- 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 0.025%

Purpose

Topical Analgesic

Keep Out of Reach of Children

If swallowed, get medical help or contact a PoisonControlCenter immediately.

Uses

- for the temporary relief of minor aches and pains of muscles and joints associated with arthritis, simple backache, strains and sprains

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, discontinue use of this product and consult a doctor
- blistering occurs
- difficulty breathing or swallowing occurs
- severe burning persists

Directions

- for persons under 18 years of age, ask a doctor before using
- apply a thin film of cream 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
- 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: **1-866-263-9003**, Mon-Thurs 9:00 am - 5:00 pm EST, Fri 9:00 am - 2:30 pm EST. Serious side effects associated with use of this product may be reported to this number.

Package/Label Principal Display Panel

ZOSTRIX ORIGINAL STRENGTH

capsaicin cream

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:61787-442

Route of Administration	TOPICAL

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
CAPSAICIN (UNII: S07O44R1ZM) (CAPSAICIN - UNII:S07O44R1ZM)	CAPSAICIN	.25 mg in 1 g

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

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:61787-442-02	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	01/09/2006	

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(61787-442)

Revised: 5/2014 Health Care Products