

**ZOSTRIX HP- 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.*

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**Drug Facts**

**Active ingredient**

Capsaicin 0.075%

**Purpose**

Topical Analgesic

**Keep Out of Reach of Children**

**Uses**

- for the temporary relief of minor aches and pains of muscles and joints associated with arthritis, simple backache, strains and sprains
- for use in treating neuralgias, consult a physician

**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.
- 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 does not improve after regular use.
- 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. 443:05 8/13

**Package/Label Principal Display Panel**



NDC 61787-443-02

ZOSTRIX®

HP HIGH POTENCY

ARTHRITIS PAIN RELIEF

ODOR FREE CREAM

Capsaicin 0.075% Topical Analgesic

NET WT 2.0 OZ. (56.6g.)

**ZOSTRIX HP**

capsaicin cream

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:61787-443
<b>Route of Administration</b>	TOPICAL		

### Active Ingredient/Active Moiety

<b>Ingredient Name</b>	<b>Basis of Strength</b>	<b>Strength</b>
CAPSAICIN (UNII: S07O44R1ZM) (CAPSAICIN - UNII:S07O44R1ZM)	CAPSAICIN	0.75 mg in 1 g

### Inactive Ingredients

<b>Ingredient Name</b>	<b>Strength</b>
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:61787-443-02	1 in 1 CARTON	01/09/2006	
1		56.6 g in 1 TUBE; Type 0: Not a Combination Product		

### Marketing Information

<b>Marketing Category</b>	<b>Application Number or Monograph Citation</b>	<b>Marketing Start Date</b>	<b>Marketing End Date</b>
OTC monograph not final	part348	01/09/2006	

**Labeler** - Health Care Products (101196749)

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

### Establishment

<b>Name</b>	<b>Address</b>	<b>ID/FEI</b>	<b>Business Operations</b>
Process Technologies & Packaging, LLC		809172885	MANUFACTURE(61787-443)