

Zostrix®
(Capsaicin 0.025%) Topical Analgesic Cream

Zostrix-HP®
High Potency
(Capsaicin 0.075%) Topical Analgesic Cream

Description: Zostrix®/Zostrix-HP® contain capsaicin, in an emollient base containing benzyl alcohol, cetyl alcohol, glyceryl monostearate, isopropyl myristate, PEG-100 stearate, purified water, sorbitol solution and white petrolatum.

Indications: Zostrix®/Zostrix-HP® are indicated 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. Do not wrap tightly. Do not get on mucous membranes, into eyes or on contact lenses. If this occurs, rinse the affected area thoroughly with water. Discontinue use of this product and consult your doctor if condition worsens or does not improve after regular use, if blistering occurs, or if severe burning persists. Do not apply heat to the treated area immediately before or after applications as this may increase the burning sensation. If you have difficulty breathing or swallowing as a result of using this product, consult your doctor immediately. **Keep this and all drugs out of the reach of children. In case of accidental ingestion, seek professional assistance or contact a Poison Control Center immediately.**

Directions: For persons under 18 years of age, ask a doctor before using. Adults and persons 18 years of age and older: 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. Unless treating hands, wash hands thoroughly with soap and water immediately after use. Refer to this package insert for more information.

How Supplied:

Zostrix®: 2.0-oz. tube (NDC 61787-442-02) & 0.265-oz. tube (NDC 61787-442-75)
Zostrix-HP®: 2.0-oz tube (NDC 61787-443-02) & 0.265-oz. tube (NDC 61787-443-75)

Store at 15°C–30°C (59°F–86°F)

Read This Important Information Before Using:

ORIGINAL
ZOSTRIX
(Capsaicin 0.025%) Topical Analgesic Cream
and
HIGH POTENCY
ZOSTRIX-HP
(Capsaicin 0.075%) Topical Analgesic Cream

First in a unique class of pain relievers:

Zostrix® and Zostrix-HP® work in a unique way. Unlike other topical pain relievers, Zostrix® relieves your pain by depleting Substance P, a chemical messenger in nerve cells that is responsible for transmitting pain signals. When Zostrix® depletes Substance P at the site of application, you feel less pain. Zostrix® and Zostrix-HP® are the only clinically tested and proven products of this kind available today, without a doctor's prescription. This is why Zostrix® is the brand of topical analgesic widely recommended by doctors and pharmacists for real arthritis pain relief.

Effective alone or when used with oral medication(s):

Clinical studies published in independent medical and scientific journals confirm that Zostrix® and Zostrix-HP® provide effective pain relief whether used alone or in conjunction with oral pain medications (NSAIDs). In a study where Zostrix® was used alone to treat arthritis pain, nearly 9 out of every 10 arthritis patients experienced significant pain relief¹. In another study, arthritis sufferers who used Zostrix® along with their oral medication experienced significantly greater pain relief and greater mobility than they did when taking their oral medication alone². What's more, you can feel comfortable knowing Zostrix® will not interfere with oral medications taken for arthritis or other conditions.

The more you use Zostrix®, the better it works: _____

For optimum pain relief, regular and frequent usage of Zostrix® or Zostrix-HP® is essential. This is because regular use of Zostrix®, as directed, helps to deplete the supply of Substance P in your nerve cells, and prevent it from building up. As Zostrix® works to deplete Substance P in your nerve cells, it begins to provide relief – becoming more and more effective as you use it regularly. Because it takes time for Substance P to be depleted, relief occurs gradually. For optimum pain relief apply Zostrix® or Zostrix-HP® 3 to 4 times daily, as directed – relief may be delayed otherwise.

- 1 Apply small amount (in a thin layer) to the painful area 3 to 4 times daily, regularly, as directed.
- 2 Massage into skin of painful area until fully absorbed and no residue remains.
- 3 If you are applying to painful areas on your hands, wait 30 minutes after application before washing hands. (Do not touch your face during this period.)
- 4 Avoid thick application. Avoid inhaling airborne material from dried residue which can cause coughing, sneezing, tearing, and/or throat or respiratory irritation. If difficulty breathing or swallowing occurs, contact a physician.
- 5 Wash hands thoroughly after application. Avoid contact with eyes, mucous membranes, and other sensitive areas of the body after use. Flush with water, if there is any contact of eyes, mucous membranes, or other sensitive areas.
- 6 Application with medical exam quality single-use latex glove, cotton ball, or Q-Tip® or equivalent applicator may help to avoid contact with eyes, mucous membranes, and other sensitive areas.
- 7 Do not apply to wounds or to damaged or irritated skin. Do not tightly wrap or bandage the treated area. Do not apply heat to the treated area.
- 8 If condition worsens or does not improve with regular usage, discontinue use of this product and consult your physician.

Zostrix® has an excellent safety profile: _____

Zostrix® has a long established safety record. There are no known serious or systemic side effects associated with Zostrix® or Zostrix-HP® when used as directed. However, some people do experience a burning sensation upon application, most often when they first begin use of Zostrix®. This sensation is more common when using triple-strength Zostrix-HP® than with use of original Zostrix®. In most cases, any burning sensation is transient and diminishes as Zostrix® or Zostrix-HP® is used consistently as directed. As long as the burning sensation is tolerable and temporary, you should not be concerned and should feel comfortable in continuing use of Zostrix® or Zostrix-HP® for relieving your pain.

Cited References: _____

- 1 Altman RD, Aven A, Holmburg CE, et al. Capsaicin cream 0.025% as monotherapy for osteoarthritis: a double-blind study. *Semin Arthritis Rheum*. 1994;23(suppl3):25-33.
- 2 Deal CL, Schnitzer TJ, Lipstein E, et al. Treatment of arthritis with topical capsaicin: a double-blind trial. *Clin Ther*. 1991;13:383-395.


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