Patient Leaflet according to the Pharmacists' Regulations (Preparations) -1986

This medicine is sold without a doctor's prescription

ZOSTRIX
CREAM

ZOSTRIX-HP
CREAM

Active ingredient:
Zostrix: Capsaicin 0.025%
Zostrix-HP: Capsaicin 0.075%

For the list of the additional ingredients, see section 6. See also 'Important information about some of the medicine's ingredients' in section 2.
Carefully read the entire leaflet before using the medicine.
This leaflet contains concise information about the medicine. If you have any further questions, please refer to your doctor or pharmacist.
Use this medicine according to the instructions in the dosage section in this leaflet. Consult the pharmacist if you require additional information.
Refer to your doctor if the illness symptoms do not improve after 28 days or if they worsen.

1. What is the medicine intended for?

Zostrix is intended for the local relief of pain associated with arthritis.
Zostrix-HP is intended for the local relief of pain associated with post-herpetic neuralgia (nerve pain due to shingles) and diabetic neuropathy.

Therapeutic group: the active ingredient capsaicin reduces transmission of pain signals to the brain. Capsaicin is a substance found in plants.

2. Before using the medicine

Do not use the medicine if:

- You are sensitive (allergic) to the active ingredient or to any of the additional ingredients the medicine contains (for the list of the additional ingredients, see section 6).
- Do not apply the cream on wounded or irritated skin.

Special warnings regarding the use of this medicine:

- Consult a doctor or pharmacist before using the medicine.
- If you are sensitive to any food or medicine, consult a doctor or pharmacist.
- Keep away from mucous membranes (such as eyes, nose, mouth). If the cream accidentally comes into contact with these areas or with wounded or irritated skin, wash off immediately with plenty of water.
- Wash your hands thoroughly immediately after applying the cream, unless the treatment is for the hands, in which case they should be washed 30 minutes after applying.
- Avoid hot showers/baths immediately before or after applying the cream.
- If the treated area requires bandaging, do not apply a tight bandage after applying the cream.
- Avoid breathing in any vapors from the cream, as this can cause irritation of the eyes and breathing difficulties (including worsening of asthma). See also 'Side effects' section.
- Patients suffering from herpes zoster should wait until the herpes blisters are gone before applying the cream.

Children and adolescents: this medicine is not suitable for children and babies.

Drug interactions:

If you are taking, or have recently taken any other medicines, including non-prescription medicines and nutritional supplements, please tell the doctor or pharmacist.

Pregnancy and breastfeeding:

If you are pregnant, think you are pregnant, are planning a pregnancy or if you are breastfeeding, consult a doctor or pharmacist before taking the medicine.

Important information about some of the medicine's ingredients:

- The cream contains 0.01 mg benzyl alcohol per milligram of cream. Benzyl alcohol may cause mild local irritation and allergic reactions.
- The cream contains cetyl alcohol, which may cause local skin reactions (for instance contact dermatitis).

3. How to use this medicine?

Check with the doctor or pharmacist if you are not sure about the dosage and manner of treatment with the medicine.

- Do not swallow. This medicine is intended for external use only.
- Do not apply on wounded skin.
- Do not apply near the eyes.
- Patients suffering from herpes zoster should wait until the herpes blisters are gone before applying the cream.

The manner of use and the standard dosage are usually:

Apply to the treated area 3 or 4 times daily, with a gap of at least 4 hours between one application to the next.

Apply a small amount of the cream (about the size of a pea) on the treated area , until the cream is absorbed and no longer visible.

A temporary burning sensation at the treated area may develop after application of the cream.

Do not exceed the recommended dose.

Wash your hands thoroughly (not in hot water) immediately after applying the cream, unless the treatment is for the hands, in which case, they should be washed 30 minutes after application.

The relief of pain begins generally in the course of the first week of treatment and increases with regular and continued application for two to eight weeks.

If your state of health worsens or if there is no improvement in your condition after 28 days, consult your doctor.

If you applied a larger amount of the cream the likelihood of experiencing a burning sensation at the application site increases.

Do not take medicines in the dark! Check the label and the dose each time you take a medicine. Wear glasses if you need them. If you have further questions concerning the use of the medicine, consult a doctor or pharmacist.

4. Side effects

As with any medicine, the use of Zostrix may cause side effects in some users. Do not be alarmed while reading the list of side effects. You may not suffer from any of them.

- The cream may cause a temporary burning sensation, that could be more frequent if too much cream is applied or if applied more than 4 times daily, or if the cream is applied shortly before or after a hot bath/shower.
- In rare cases, while applying the cream, the vapors may cause brief irritation of the eyes, and the respiratory system such as the nose and throat manifested in symptoms

such as tearing, runny nose, cough, sneezing. Shortness of breath, wheezing or worsening of asthma have also been reported.
- The cream may cause skin irritation and manifest in symptoms such as itching or stinging.

If a side effect appears, if one of the side effects worsens, or if you suffer from a side effect not mentioned in the leaflet, consult with the doctor.

Side effects may be reported to the Ministry of Health by clicking on the link "Report on side effects following medicinal treatment" on the homepage of the Ministry of Health website (www.health.gov.il) which leads to an online form for reporting side effects, or by entering the link: https://sideeffects.health.gov.il/

5. How to store the medicine?

- Avoid poisoning! This medicine, and any other medicine, must be stored in a closed place out of the reach and sight of children and/or infants, to avoid poisoning. Do not induce vomiting unless explicitly instructed to do so by the doctor.
- Do not use the medicine after the expiry date (exp. date) that appears on the package. The expiry date refers to the last day of that month.
- Storage conditions: store below 25°C.
- After the first opening of the tube, the cream may be used within 3 months, but no later than the expiry date marked on the package.

6. Additional information

In addition to the active ingredient, the medicine also contains:
Sorbitol, cetyl alcohol, isopropyl myristate, stearoyl macrogolglycerides, white soft paraffin, benzyl alcohol, water.

What does the medicine look like and what does the package contain?
A white cream in a tube. Every tube contains 30 grams.

Manufacturer and registration holder: Rafa Laboratories Ltd., P.O. Box 405, Jerusalem 9100301.

Medicine registration number in the National Medicines Registry of the Ministry of Health:
Zostrix 1012028410
Zostrix-HP 1012128411

Revised in August 2021 according to the Ministry of Health's guidelines.

260005