

PATIENT PACKAGE INSERT IN ACCORDANCE WITH THE PHARMACISTS' REGULATIONS - (PREPARATIONS) - 1986

The dispensing of this medicine requires a physician's prescription

Read this package insert carefully in its entirety before using this medicine

The format of this leaflet was determined by the Ministry of Health and its content was checked and approved by it in December 2009

isoket® spray

Composition:

Active ingredients and their strength:

Each dose contains:

Isosorbide dinitrate 1.25 mg

Inactive ingredients:

Ethanol, Macrogol 400

Therapeutic group:

Nitrate vasodilators.

Therapeutic activity:

For the prevention and treatment of angina pectoris.

Isoket spray can be used to prevent an attack before expected physical exertion or mental stress.

When should the medicine not be used?

Do not use this medicine if you know of sensitivity to any of its ingredients.

Do not use this medicine in cases of heart muscle disease (cardiomyopathy), inflammation of the pericardium (pericarditis) or accumulation of extra fluid in the pericardium (cardiac tamponade).

Do not use in patients who suffer from impaired circulatory function or from especially low blood pressure.

Do not use concomitantly with medicines of the PDE5 inhibitor group (medicines for the treatment of erectile dysfunction) such as Viagra, Cialis and Levitra in light of the severe side effects that may occur (such as fainting, myocardial infarction).

Do not use this medicine without consulting a physician before starting treatment in the following cases:

If you are pregnant or breastfeeding.

If you are suffering, or have suffered in the past, from impaired function of the heart and/or vascular system or if you have suffered a recent heart attack, the eyes (e.g. glaucoma), the liver, the kidney/urinary tract, the digestive system (e.g. ulcer), the thyroid gland, the blood system (e.g. coagulation, etc.), hypotension, severe anemia, in cases of high intracranial pressure or in cases of cerebral trauma or hemorrhage.

How will this medicine affect your daily life?

Use of this medicine may affect the ability to react and therefore caution should be exercised when driving a car, operating dangerous machinery and in any activity which requires alertness.

Do not drink wines or alcoholic beverages while under treatment with this medicine.

Warnings:

During treatment with this medicine, you should perform heart function and blood pressure tests.

If you are sensitive to any type of food or medicine, inform your physician before taking this medicine.

Avoid sudden transition from a lying/sitting

position to a standing position in order to prevent dizziness and in extreme cases, fainting.

Drug interactions:

If you are taking another medicine, or if you have just finished treatment with another medicine, inform the attending physician, in order to prevent hazards or lack of efficacy arising from drug interactions, especially for medicines from the following groups: medicines affecting the central nervous system (from the anti-psychotics group), antidepressants, antihypertensives (e.g. beta blockers, calcium channel blockers and vasodilators), cough and cold medications, antimigraine medicines (at high dosages), medicines for the treatment of erectile dysfunction (e.g. Viagra, Cialis, Levitra).

Side effects:

In addition to the desired effect of the medicine, side effects may occur during the course of treatment with this medicine, such as: headaches - a common effect that usually passes during treatment, a drop in blood pressure when standing up, nausea or vomiting, dizziness, drowsiness, feeling of weakness, increased heartbeat, paleness, restlessness, excessive sweating, burning sensation of the tongue in the sprayed area.

Side effects that require special attention:

Skin irritation, redness or rash, prolonged headache, falling or fainting (rare): stop treatment and refer to the physician.

Side effects that result from an overdose:

Increased weakness, bluish-tinged lips, fingernails or palms of hands, pressure in the head (rare): stop treatment and refer to the physician.

In the event that you experience side effects not mentioned in this leaflet, or if there is a change

in your general health, consult your physician immediately.

Dosage:

Dosage is according to the physician's instructions only and will be adjusted individually for each patient.

The general recommendation is 1-3 actuations at 30 second intervals into the mouth during an attack or before expected exertion.

Do not exceed the recommended dosage.

This medicine is not usually intended for children and infants.

Attention:

The solution contains 85% v/v ethanol, therefore, appropriate storage conditions must be ensured and it must be kept away from a source of heat/fire.

In case the spray solution comes into contact with a wide area of skin, clean the exposed area immediately!

Directions for use:

Important! Spray the solution into the mouth. Do not inhale the spray.

1. Before beginning of use, prepare the top of the bottle-dosing pump for use, by pumping lightly several times until a single even actuation is released into the air. Now the spray is ready for use.
2. If you have not used the spray for more than one day, the first squirt has to be released into the air in order to ensure a full and even dose.
3. During application, hold the bottle with the pump facing upward (opposite the mouth). Inhale deeply, hold your breath, pressing the pump and spray into the mouth (this may induce a slight burning sensation on the tongue). Close your mouth and continue breathing only through the nose for about 30 seconds.

How can you contribute to the success of the treatment?

Complete the full course of treatment as instructed by the physician.

Avoid poisoning!

This medicine, and all other medicines, must be stored in a safe place out of the reach of children and/or infants, to avoid poisoning.

If you have taken an overdose, or if a child has accidentally swallowed the medicine, proceed immediately to a hospital emergency room and bring the package of the medicine with you.

Do not induce vomiting unless explicitly instructed to do so by a physician!

This medicine has been prescribed for the treatment of your ailment, in another patient it may cause harm. **Do not give this medicine to your relatives, neighbors or acquaintances.**

Do not take medicines in the dark! Check the label and the dose **each time** you take your medicine. Wear glasses if you need them.

Storage:

Store below 30°C.

Caution! Inflammable, keep away from fire.

Even if kept in their original container and stored as recommended, medicines may be kept for a limited period only. Please note the expiry date of the medicine! In case of doubt, consult the pharmacist who dispensed the medicine to you.

Do not store different medications in the same package.

License number: 38-49-22386

Manufacturer:

Aesica Pharmaceuticals GmbH, Monheim, Germany.

License Holder and Importer:

GlaxoSmithKline (Israel) Ltd., 25 Basel St., Petach Tikva.

