

User information, please read carefully!

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POHL

Nitrolingual-S[®] pray 0.4 mg/dose

Active ingredient: glyceryl trinitrate

Composition: 1 puff of the spray contains 0.4 mg glyceryl trinitrate. Other constituents: medium-chain triglycerides, medium-chain partial glycerides, absolute ethanol, peppermint oil.

Indications:

- ⊘ Treatment of all forms of episodic cardiac pain (relief of angina pectoris attacks);
- ⊘ As a prophylactic measure immediately prior to physical exertion or other situations known from experience to be capable of triggering episodic cardiac pain (prophylaxis of angina pectoris);
- ⊘ Acute cardiac infarction;
- ⊘ Acute left-heart failure (acute myocardial insufficiency, with acutely impaired left ventricular function);
- ⊘ Catheter-induced coronary spasms during coronary angiography.

Contraindications:

Glyceryl trinitrate must not be used in patients with:

- ⊘ Hypersensitivity to one of the components of the drug;
- ⊘ Acute circulatory failure (shock, circulatory collapse);
- ⊘ Severe hypotension (systolic blood pressure below 90 mm Hg);
- ⊘ Cardiogenic shock, unless intra-aortic counterpulsation or positively inotropic drugs ensure an adequately high left-ventricular end-diastolic pressure;
- ⊘ Myocardial disorders, with a reduction of the heart volume (hypertrophic obstructive cardiomyopathy);
- ⊘ Constrictive pericarditis;
- ⊘ Pericardial tamponade;
- ⊘ Patients with primary pulmonary hypertension (high blood pressure in the pulmonary circulation of unknown causation), since a possible increase in the blood supply to hypoventilated alveolar regions (hypoventilated regions of the lungs) can lead to hypoxaemia (reduction in the oxygen concentration in the arterial blood). This applies in particular to patients with disturbances of the blood flow in the coronary vessels (coronary heart disease).
- ⊘ Due to a considerable increase in the hypotensive effect and the resulting severe side effects (e.g. syncope, myocardial infarction), sildenafil (Viagra) may not be given additionally to an existing therapy with nitric oxide donors (e.g. Nitrolingual-S pray).

Especially careful medical supervision is required in patients with:

- ⊘ Acute cardiac infarction with low filling pressures. Nitrolingual-S pray must always be used with caution in such cases; a reduction of the systolic blood pressure to below 90 mm Hg must be avoided.
- ⊘ Aortic and/or mitral stenosis;
- ⊘ A tendency to disturbances of regulation of the circulation due to hypotension (orthostatic disturbances of circulatory regulation);
- ⊘ Diseases associated with increased intracranial pressure (further elevation of the blood pressure has so far been observed only in association with high-dose i.v. administration of glyceryl trinitrate).

During pregnancy and breastfeeding, as an extra precaution glyceryl trinitrate must only be taken if expressly directed by the doctor. Experiments in animals have yielded no evidence of damage to the foetus.

Side effects:

Headache (nitrate-induced headache) is common at the start of the treatment. Experience has shown that this usually subsides as administration of the substance is continued.

A decline in the blood pressure and/or orthostatic hypotension have occasionally been observed when the substance is first used, and also when the dose is increased. This may be associated with a reflex increase in the heart rate, drowsiness and a sensation of dizziness and weakness.

Nausea, vomiting, transient reddening of the skin (flush) and allergic cutaneous reactions may occur in rare cases.

Collapse states are observed in rare cases, occasionally with bradycardial disturbances of heart rhythm, and syncope. Exfoliative dermatitis may occur in individual cases.

In rare cases, a pronounced decline in the blood pressure may be linked to increased severity of the symptoms of angina pectoris.

Tolerance development and the occurrence of cross tolerance to other nitro compounds have been described. Attenuation of the haemodynamic effects has been observed within 24 h, even during continuous administration.

Even when used as directed, this drug may alter the reactions to such an extent that the ability to drive or operate machinery is impaired. This applies in particular when the effects are combined with alcohol.

Interactions with other drugs:

The following interactions of this drug must be borne in mind:

The simultaneous ingestion of other vasodilators, substances which lower the blood pressure (antihypertensives), β -blockers, calcium antagonists, neuroleptics or tricyclic antidepressants, and alcohol may potentiate the hypotensive action of Nitrolingual[®]-S spray.

Concomitant intake of nitric-oxide-donors (e.g. Nitrolingual[®]-S spray) and sildenafil (Viagra) enhances the hypotensive effect. Therefore the concomitant administration of nitric-oxide-donors, e.g. the active ingredients of Nitrolingual[®]-S spray, and Viagra, is contra-indicated (see contra-indications).

If a patient treated with sildenafil (Viagra) needs a rapidly effective nitrate (e.g. in case of an acute angina pectoris attack) he/she must be hospitalised immediately.

In patients previously treated with organic nitrates (e.g. isosorbide dinitrate, isosorbide-5-mononitrate), a higher dose of glyceryl trinitrate may be necessary to achieve the desired haemodynamic effect. During the simultaneous use of dihydroergotamine, Nitrolingual[®]-S spray may lead to an increase in the DHE level and thus potentiate its hypertensive action. When heparin and glyceryl trinitrate are used simultaneously the effects of heparin are reduced.

Dosage guideline: Unless otherwise prescribed, at the start of an angina pectoris attack or immediately before exercise known from experience to be capable of triggering an attack of angina pectoris, depending on the severity 0.4 mg - 0.8 mg glyceryl trinitrate is administered, corresponding to 1-2 puffs of the spray. In patients with acute left-heart failure or acute cardiac infarction, while monitoring the circulatory parameters (systolic blood pressure in excess of 100 mm Hg) 0.4 mg - 1.2 mg glyceryl trinitrate is administered depending on the severity, corresponding to 1-3 puffs of the spray. If there is no response after 10 min the treatment may be repeated at the same dose. For prophylaxis prior to coronary angiography, 0.4 mg - 0.8 mg glyceryl trinitrate is administered, corresponding to 1-2 puffs of the spray.

Nature and duration of use: Before each use, remove the protective cap by pulling it off in a vertically upwards direction. To familiarise oneself with the use of Nitrolingual[®]-S spray and to fill the dose-metering chamber completely when first using, the valve is first of all operated once and the contents sprayed into the air (press the spray nozzle down smoothly as far as it will go, and then release). This may also be necessary if the spray has not been used for a long time. The spray is now ready to use, and needs not to be shaken first.

When spraying, hold the bottle vertically with the spray nozzle uppermost. Position the orifice in the spray nozzle as close as possible to the mouth. This orifice is easily felt, and can therefore also be used as a reliable indicator of the bottle orientation when using the substance at night. The spray is puffed into the mouth, preferably under the tongue, at intervals of about 30 sec while holding the breath. Do not inhale.

General information: The transparent container can be used for continuous monitoring of the consumption. A new Nitrolingual[®]-S spray should be obtained in good time, before the end of the delivery tube is no longer covered by the fluid level. As with all other sprays, there is a residual volume of fluid at the bottom of the bottle which cannot be used. Nitrolingual[®]-S spray must not be used after the expiry date. Do not force open or burn after use. Do not spray on to naked flames or incandescent objects.

Keep all medicines out of the reach of children.
