

Nitrosol®

Nitroglycerin Aerosol
Spray



Description

Nitrosol® Aerosol is a metered dose spray containing Glyceryl Trinitrate BP. Each actuation delivers Glyceryl Trinitrate BP 400 mcg.

Clinical Pharmacology

The principal pharmacological action of nitroglycerin is relaxation of vascular smooth muscle, producing a vasodilator effect on both peripheral arteries and veins with more prominent effects on the latter. Dilation of the post-capillary vessels, including large veins, promotes peripheral pooling of blood and decreases venous return to the heart, thereby reducing left ventricular end-diastolic pressure (pre-load). Arteriolar relaxation reduces systemic vascular resistance and arterial pressure (after-load).

Indications and Usage

Nitrosol® Aerosol is indicated for acute relief of an attack or prophylaxis of angina pectoris due to coronary artery disease.

Dosage and Administration

At the onset of an attack, one or two metered sprays should be administered under the tongue. No more than three metered sprays are recommended within a 15-minute period. If the chest pain persists, prompt medical attention is recommended. Nitrosol® Aerosol may be used prophylactically five to ten minutes prior to engaging in activities which might precipitate an acute attack.

Contraindications

Nitroglycerin is contraindicated in patients who are allergic to it. Nitrosol® Aerosol is contraindicated in patients taking certain drugs for erectile dysfunction (phosphodiesterase inhibitors), Hypotensive Shock, Narrow-angle Glaucoma, Severe anaemia, Cerebral haemorrhage and brain trauma.

Side Effects

Transitional, mild burning sensation in the mouth. Pulsation in the head, facial flush, headache, dizziness, palpitation, sensation of heat, nausea, sweating. Mainly at overdosage, methemoglobinemia and cyanosis may occur.

Precautions

Severe hypotension, particularly with upright posture, may occur even with small doses of nitroglycerin. The drug, therefore, should be used with caution in subjects who may have volume depletion from diuretic therapy or in patients who have low systolic blood pressure (e.g., below 90 mm Hg). Paradoxical bradycardia and increased angina pectoris may accompany nitroglycerin-induced hypotension. Nitrate therapy may aggravate the angina caused by hypertrophic cardiomyopathy. **PREGNANCY:** Pregnancy Category C. **NURSING MOTHERS:** It is not known whether nitroglycerin is excreted in human milk. **PEDIATRIC USE:** Safety and effectiveness of nitroglycerin in pediatric patients have not been established.

Drug Interactions

It should be applied with precaution together with antihypertensive, tricyclic antidepressants (hypotension is enhanced)

Pharmaceutical Precautions

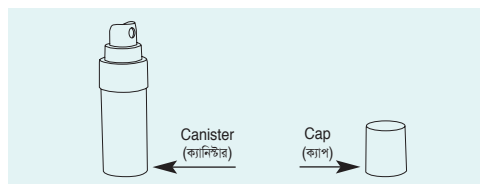
Do not puncture, break or incinerate even when the canister is empty. Avoid storage in direct sunlight or heat. Store below 25°C. Keep out of reach of children. To be dispensed only on the prescription of a registered doctor.

Commercial Pack

Each pack contains one canister of Nitrosol®. Each canister of Nitrosol® contains minimum 200 doses. Each actuation delivers Glyceryl Trinitrate BP 400 mcg.



Manufactured by
BEXIMCO PHARMACEUTICALS LTD.
Tongi, Bangladesh 500061 140507
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How to use Nitrosol® Aerosol

Practice first. You may wish to use urgently or in the dark. So, if you have never used it before, practice spraying a few puffs into the air.

- ◆ Sit down if possible
- ◆ Remove the cap. Hold the aerosol upright with forefinger on top of the white button
- ◆ Open your mouth and bring as close as possible, aiming it under the tongue.
- ◆ Press the button firmly, directing the aerosol under the tongue.
- ◆ Close your mouth immediately but do not breathe the medicine in
- ◆ If necessary, repeat for a second time following the steps above

Doses counter (মাত্রা পরিমাপক): প্রতিবার মাত্রা গ্রহণের পর নিম্নের বাসে সঠিক মাত্রা সংখ্যাটি চিহ্নিত করুন।

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