



Nitrosol®

Sublingual Aerosol Spray 400 mcg/actuation



Vasodilator

Each Actuation Delivers:
Glyceryl Trinitrate BP 400 mcg

PRODUCT DESCRIPTION

It is a clear solution of Glyceryl Trinitrate which is filled into aluminium can fitted onto a valve. The propellant 1, 1, 1, 2- Tetrafluoroethane (HFA 134a) is then filled into the can through valve. The can fitted with valve is then again fitted with an actuator, collar and safety hood. This is then packed inside an inner carton with leaflet inside.

PHARMACODYNAMICS

Glyceryl trinitrate relieves angina pectoris by reduction of cardiac work and dilation of the coronary arteries. In this way, not only is there a lessening in arterial oxygen requirement but the amount of oxygenated blood reaching the ischaemic heart is increased.

PHARMACOKINETICS

The pharmacokinetics of glyceryl trinitrate are complex; venous plasma levels of the drug show wide and variable fluctuations and are not predictive of clinical effect. In a human pharmacodynamic study, pharmacological activity had commenced one minute after dosing and was obvious by two minutes.

INDICATION

For the treatment and prophylaxis of angina pectoris and the treatment of variant angina.

RECOMMENDED DOSE

At the onset of an attack, one or two metered sprays should be administered on or under the tongue. A spray may be repeated approximately every 5 minutes as needed. No more than 3 metered sprays are recommended within a 15 minute period. If chest pain persists after a total of 3 sprays, prompt medical attention is recommended. Nitrosol® may be used prophylactically 5 to 10 minutes before engaging in activities that might precipitate an acute attack.

MODE OF ADMINISTRATION

Sublingual

During use the patient should rest, ideally in the sitting position. The container should be held vertically with the valve head uppermost and the spray orifice as close to the mouth as possible. The dose should preferably be sprayed into the mouth on or under the tongue by pressing the button firmly and the mouth should be closed immediately after each dose. The spray should not be inhaled. Patients should be instructed to familiarize themselves with the position of the spray orifice, which can be identified by the finger rest on top of the valve, in order to facilitate orientation for administration at night.

- ◆ 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.

CONTRAINDICATION

Hypersensitivity to nitrates or any constituent of the formulation. Hypotension, hypovolaemia, severe anaemia, cerebral haemorrhage and brain trauma, mitral stenosis and angina caused by hypertrophic obstructive cardiomyopathy. Concomitant administration of

phosphodiesterase inhibitors used for the treatment of erectile dysfunction.

WARNING AND PRECAUTIONS

Any lack of effect may be an indicator of early myocardial infarction. As with all glyceryl trinitrate preparations, use in patients with incipient glaucoma should be avoided.

INTERACTIONS WITH OTHER MEDICAMENTS

Tolerance to this drug and cross tolerance to other nitrates may occur. Alcohol may potentiate any hypotensive effect.

The hypotensive effects of nitrates are potentiated by concurrent administration of phosphodiesterase inhibitors used for the treatment of erectile dysfunction. A severe and possibly dangerous fall in blood pressure may occur. This can result in collapse, unconsciousness and may be fatal. Such use is therefore contra-indicated.

If a patient treated with these drugs for erectile dysfunction needs a rapidly effective nitrate, he/she should be closely monitored.

PREGNANCY AND LACTATION

Not generally recommended and should be used only if its potential benefit justifies any potential risk to the foetus or neonate.

SIDE EFFECT

Headache, dizziness, postural hypotension, flushing, tachycardia and paradoxical bradycardia have been reported.

SYMPTOMS AND TREATMENT OF OVERDOSE

Signs and symptoms:

Flushing, severe headache, a feeling of suffocation, hypotension, fainting, restlessness, blurred vision, impairment of respiration, bradycardia and rarely, cyanosis and methaemoglobinaemia may occur. In a few patients there may be a reaction comparable to shock with nausea, vomiting, weakness, sweating and syncope.

Treatment:

Recovery often occurs without special treatment. Hypotension may be corrected by elevation of the legs to promote venous return. Methaemoglobinaemia should be treated by intravenous methylene blue.

Symptomatic treatment should be given for respiratory and circulatory defects in more serious cases.

If methaemoglobinaemia is present, intravenous administration of methylene blue, 1 to 2 mg/kg of body weight, may be required.

STORAGE

Store below 30°C.

Keep medicines out of the reach of children.

SHELF-LIFE

3 years.

SUPPLY

Available in 100 & 200 metered doses..

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Manufactured by
BEXIMCO PHARMACEUTICALS LTD.
126, Kathaldia, Auchpara, Tongi, Gazipur, BANGLADESH
Imported / Distributed by: **MEDISPEC (M) SDN BHD**
No. 55 & 57, Lorong Sempadan 2, (Off Boundary Road)
11400 Ayer Itam, Penang, MALAYSIA

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