

NITROSOL SUBLINGUAL AEROSOL SPRAY

400mcg/actuation

Glyceryl Trinitrate BP 400 mcg.

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What Nitrosol® is used for

Nitrosol® is a metered dose spray containing Glyceryl Trinitrate BP which is used for the treatment and prevention of chest pain and the treatment of variant angina (a type of chest pain). Glyceryl trinitrate belongs to a group of medicines called nitrates.

How Nitrosol® works

Nitrosol® relieves chest pain by reduction of heart muscle work and dilation of the blood vessels to the heart. In this way not only there is a lessening in blood vessel oxygen requirement but the amount of oxygenated blood reaching the heart is increased.

Before you use Nitrosol®

When you must not use it

You should not use Nitrosol® if you have any of the following conditions:

- Known allergy or sensitivity to nitrates or any of the other components of Nitrosol.
- An eye disease called glaucoma
- Low iron levels in your blood or low red blood cell count (severe anemia)
- Low blood pressure (hypotension)
- Hypovolaemia (severe blood and fluid loss)
- Cerebral haemorrhage (bleeding in the brain)
- Brain trauma (injury to the brain)
- Mitral stenosis (narrowing of a heart valve)
- Chest pain caused by hypertrophic obstructive cardiomyopathy (abnormally thickened heart muscle)

Pregnancy and lactation

Do not take Nitrosol® if you are pregnant, trying to get pregnant or think you may be pregnant.

Do not take Nitrosol® if you are breast-feeding. Ask your doctor or pharmacist for advice before taking any medicine.

- Before you start to use it

BEFORE you use Nitrosol® talk to your doctor or pharmacist if:

- You are currently taking any other medications, whether on prescription or otherwise.
- You have headaches, weakness or dizziness especially when getting up suddenly from a laying down or sitting position, or symptoms of low blood pressure (hypotension)
- You are breast feeding, pregnant, or think you might be pregnant
- You had a heart attack

- Taking other medicines

Nitrosol may interact with certain drugs such as alcohol and phosphodiesterase inhibitor (used in erectile dysfunction).

Tell your doctor if you are taking any other medicines, including any that you buy without a prescription from a pharmacy, supermarket or health food shop.

How to use Nitrosol®

- How much to use

At the onset of an attack, one or two metered sprays should be administered on or under the tongue.

Administration of Nitrosol sublingual aerosol spray:

1. Sit down if possible
2. Remove the cap. Hold the aerosol upright with forefinger on top of the white button.
3. Open your mouth and bring as close as possible, aiming it under the tongue.
4. Press the button firmly, directing the aerosol under the tongue.

5. Close your mouth immediately but do not breathe the medicine in.

Learn to use this spray before a chest pain happen as you may need to use it in a hurry.

Follow all directions given to you by your doctor and pharmacist carefully. They may differ from the information contained in this leaflet. If you do not understand the instructions on the label, ask your doctor or pharmacist for help.

- When to use it

A spray may be repeated approximately every 5 minutes as needed. Nitrosol may be used for prevention 5 to 10 minutes before engaging in activities that might cause an acute attack.

- How long to use it

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.

- If you forget to use it

Consult your doctor or pharmacist on what you should do if you forget to use it.

- If you use too much (overdose)

Contact your doctor immediately or go to the Emergency Department of your nearest hospital, if you think you or anyone else may have taken too much of this medicine. Do this even if there are no signs of discomfort or poisoning. You may need urgent medical attention.

While you are using it

- Things you must do

Keep a spare handy at all times as it can be difficult to tell how many doses are left in the canister

Always use this spray exactly as explained in this leaflet or when it was prescribed. You should check with

your doctor or pharmacist if you are not sure.

Tell all the doctors, dentists and pharmacists treating you that you are taking Nitrosol®

Tell your doctor immediately if you become pregnant while taking this medication.

- Things you must not do

Do not stop taking the medicine unless advised by your doctor.

Do not use this spray if you are near a naked flame, e.g. a cigarette.

Do not give Nitrosol® to anyone else, even if they have the same symptoms or condition as you.

- Things to be careful of

Any lack of effect may be an indicator of early heart attack.

After using this spray, rest for a while. When you stand up, rise slowly, as you may feel faint.

Side effects

Like all medicines, Nitrosol® can cause side effects, although not everybody gets them. Headache, dizziness, postural hypotension (low blood pressure due to change of position), flushing, tachycardia (abnormally fast heart beat) and paradoxical bradycardia (abnormally slow heart beat occasionally) have been reported.

Visit your doctor or pharmacist immediately if you experience any of the side effects listed or not listed here after taking this medicine.

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by calling Tel: 03-78835550, or visiting the website portal.bpfk.gov.my (Consumers →Reporting).

Storage and Disposal of Nitrosol®

- Storage

Keep out of the reach and sight of children.

Store below 25 °C.

- Disposal

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

Product Description

- What it looks like

It is a clear solution of Glyceryl Trinitrate which is filled into aluminium can fitted onto a valve. The propellant (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.

- Ingredients

- Active ingredient
- Glyceryl Trinitrate BP

- Inactive ingredients
- Peppermint Oil
- Tetra-fluoro ethane (HFA 134a)
- Dehydrated alcohol USP

- MAL number:

MAL09122776AZ

Manufacturer

Beximco Pharmaceuticals Ltd
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Product Registration Holder

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