

Nitrolingual® Pumpspray

Glyceryl Trinitrate

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about Nitrolingual Pumpspray. It does not contain all the available information.

It does not take the place of talking to your doctor or pharmacist.

All medicines have risks and benefits. Your doctor or pharmacist has weighed the risks of you using this medicine against the benefits they expect it will have for you.

If you have any concerns about using this medicine, ask your doctor or pharmacist.

Keep this leaflet with the medicine.

You may need to read it again.

What Nitrolingual Pumpspray is used for

Nitrolingual Pumpspray is used to treat angina.

Nitrolingual Pumpspray may also be used to prevent angina if used 5-10 minutes before taking part in an activity which may provoke an attack of angina.

Angina is a pain or uncomfortable feeling in the chest, often spreading to the arms or the neck and sometimes to the shoulders and back. This may be caused by too little blood and oxygen getting to the heart.

The pain of angina is usually brought on by exercise or stress.

Nitrolingual Pumpspray belongs to a group of medicines called nitrates. It works by widening blood vessels,

letting more blood and oxygen reach the heart.

Your doctor or pharmacist may have recommended Nitrolingual Pumpspray for another reason.

Ask your doctor or pharmacist if you have any questions about why Nitrolingual Pumpspray has been recommended for you.

There is no evidence to suggest that Nitrolingual Pumpspray is addictive.

Before you use it

When you must not use it

Do not use Nitrolingual Pumpspray if you are allergic to:

- Glyceryl trinitrate (the active ingredient) or any of the other ingredients of Nitrolingual Pumpspray listed at the end of this leaflet
- any medicine or food containing nitrates or nitrites

Symptoms of an allergic reaction may include:

- asthma, wheezing or shortness of breath
- swelling of the face, lips or tongue which may cause difficulty in swallowing or breathing
- hives, itching or skin rash
- fainting

Do not use phosphodiesterase inhibitors (e.g. Viagra®, Cialis®, Levitra® or others) if your doctor or pharmacist has asked you to use Nitrolingual Pumpspray.

Do not use soluble guanylate cyclase stimulators (such as

Adempas®) if you are using Nitrolingual Pumpspray.

Do not use Nitrolingual Pumpspray after the expiry date (EXP) printed on the bottle and packaging.

If you take this medicine after the expiry date has passed, it may not work (as well).

Do not use Nitrolingual Pumpspray if the packaging is torn or shows signs of tampering.

Do not use Nitrolingual Pumpspray to treat any other complaints unless your doctor or pharmacist has instructed you to do so.

If you are not sure whether you should start using Nitrolingual Pumpspray, contact your doctor or pharmacist.

Before you start to use it

Tell your doctor or pharmacist if:

- **you have any allergies to:**
 - any other medicines
 - any other substances, such as foods, dyes or preservatives.
 - **you have any medical conditions, including:**
 - severe anaemia
 - low blood pressure (which can make you feel faint, weak or dizzy, especially when you stand up suddenly)
 - a recent heart attack or other serious heart disease
 - a recent head injury or stroke
 - an abnormality of haemoglobin (a pigment in your red blood cells which carries oxygen)
 - high blood pressure in the pulmonary artery.
- It may not be safe for you to use Nitrolingual Pumpspray if you

have any of these medical conditions.

- **you are pregnant or intend to become pregnant.**
- **you are breast-feeding or plan to breast-feed.**

Do not use Nitrolingual Pumpspray if you are pregnant or breast-feeding unless you and your doctor or pharmacist have discussed the risks and benefits involved.

If you have not told your doctor or pharmacist about any of these things, tell them before you use Nitrolingual Pumpspray.

Taking other medicines

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

Some medicines may interfere with Nitrolingual Pumpspray. These include:

- drugs which expand the blood vessels
- drugs which lower blood pressure
- drugs which help to reduce the amount of excess fluid in the body by increasing the amount of urine produced
- drugs used to treat impaired sexual function
- drugs used to treat high blood pressure in the pulmonary artery
- some drugs for mental conditions
- some drugs used to treat depression.
- some drugs used to treat migraine headaches.
- heparin, used to thin the blood.
- ademapas® used for pulmonary hypertension

These medicines may be affected by Nitrolingual Pumpspray or may affect how well it works.

You may need to take different amounts of your medicine or you

may need to take different medicines.

Talk to your doctor or pharmacist about this.

If you have been prescribed a phosphodiesterase 5 inhibitor (e.g. Viagra®, Cialis®, Levitra® or others) for the treatment of erectile dysfunction or high blood pressure in the pulmonary artery and you experience an acute angina attack, immediately go to the emergency department at your nearest hospital.

Your doctor or pharmacist can advise further on the list of medicines to avoid while taking Nitrolingual Pumpspray.

Nitrolingual Pumpspray can be used with other medications which are used to prevent angina.

If your doctor or pharmacist transfers you from glyceryl trinitrate tablets to Nitrolingual Pumpspray you may receive a larger dose of the drug than usual, because Nitrolingual Pumpspray does not break down as quickly as glyceryl trinitrate tablets. As a result you may get more side effects.

Tell your doctor or pharmacist if you notice this.

Your doctor or pharmacist can tell you what to do if you are taking any other medicines.

Use in Children

Nitrolingual Pumpspray is not recommended for use in children as there is no specific information about such use.

Always ask your doctor or pharmacist before giving medicines to children.

Use in Elderly

Elderly patients may be more sensitive to the effects or side effects of Nitrolingual Pumpspray.

If you are elderly you may need to watch carefully for signs of side effects.

How to use it

How much to use

Your doctor or pharmacist will tell you how much Nitrolingual Pumpspray to use.

Use the exact amount your doctor or pharmacist tells you to.

At the first sign of an angina attack, one metered dose should be sprayed under your tongue. If the pain persists after five minutes, administer a second metered dose.

DO NOT TAKE MORE THAN TWO DOSES DURING AN ANGINA ATTACK.

If this does NOT relieve the angina and the pain continues, then you should call an ambulance or the nearest hospital immediately.

When to use it

Your doctor or pharmacist will tell you how often you should use Nitrolingual Pumpspray.

Nitrolingual Pumpspray is NOT a medication which is taken regularly. It is used when you need to obtain relief from the pain of an acute attack of angina.

Nitrolingual Pumpspray may also be used 5 to 10 minutes before taking part in exercise or activities which may provoke an acute attack of angina.

The number of times that you can use Nitrolingual Pumpspray in any one day will depend on how severe your angina is, what other medicines you are taking and any other medical conditions you may have. You should discuss this with your doctor or pharmacist.

How to use it

Follow the instructions for using Nitrolingual Pumpspray to make sure that you receive the correct dose.

In order to completely fill the dosing chamber when using the spray for the first time, press the

nozzle five times (quickly and completely), spraying into the air. This is called priming. If the product has not been used for one week, a priming of 1 spray is necessary. If the product has not been used for more than 4 months, a priming of 5 sprays is necessary.

The spray is then ready for use.

1. Sit down and rest.
2. Remove the plastic cover and hold the bottle upright with your forefinger on top of the grooved nozzle. There is no need to shake the bottle.
3. Open your mouth and bring the bottle as close as possible, aiming it under your tongue.
4. Press the nozzle firmly with your forefinger to release the spray under your tongue.

Do not inhale the spray.

5. Release the nozzle and close your mouth. Avoid swallowing immediately after taking a dose.
6. For a second dose repeat the above steps.
7. Replace the plastic cover after use.

It is important to familiarise yourself with the position of the spray opening and nozzle for ease of use at night.

IMPORTANT: The delivery tube must be immersed in the liquid. The contents of the bottle can only be sprayed as long as the opening at the bottom of the delivery tube is completely immersed in liquid.

What to expect

After one or two metered doses of Nitrolingual Pumpspray you should obtain relief from the pain of angina. If no relief is obtained and the pain continues you should call an ambulance or go to the nearest hospital immediately.

How long to use it

You may need to use Nitrolingual Pumpspray for as long as you

continue to suffer from angina attacks.

If you take too much (overdose)

Immediately telephone your doctor, or the Poisons Information Centre (telephone 13 11 26) for advice, or go to Accident and Emergency at your nearest hospital, if you think you or anyone else may have used too much Nitrolingual Pumpspray. Do this even if there are no signs of discomfort or poisoning. You may need urgent medical attention. Keep these telephone numbers handy.

If you use too much Nitrolingual Pumpspray, you may suffer severe headaches. Your skin may become flushed or clammy, you may have trouble seeing or you may feel flushed, nauseous (sick), dizzy, lightheaded or faint. Your heart may also beat faster or slower than usual.

While you are using it

Things you must do

Use Nitrolingual Pumpspray exactly as your doctor or pharmacist has recommended.

If you do not follow your doctor or pharmacist's instructions, you may not get relief from your angina attack.

Tell your doctor or pharmacist if you continue to have angina attacks or if they become more frequent while you are using Nitrolingual Pumpspray.

You may find it helpful to keep a written record of the number, causes, length and severity of your angina attacks, so you can tell your doctor or pharmacist at your next visit. This will help your doctor or pharmacist to choose the best possible treatment for your angina.

Tell your doctor or pharmacist immediately if you become

pregnant while using Nitrolingual Pumpspray.

Tell all doctors, dentists and pharmacists who are treating you that you are using Nitrolingual Pumpspray, especially if you are being started on any new medicines.

Tell your doctor or pharmacist that you are taking Nitrolingual Pumpspray if you are about to be started on any new medicines.

Things you must not do

Do not use Nitrolingual Pumpspray to treat any other complaints unless your doctor or pharmacist tell you to.

Do not give this medicine to anyone else even if their symptoms seem similar to yours.

Do not suddenly stop using Nitrolingual Pumpspray if you have been using large amounts of the spray regularly.

If you have been using large amounts of Nitrolingual Pumpspray regularly and stop using it suddenly, you may find that your attacks of angina become worse. If you want to stop using Nitrolingual Pumpspray ask your doctor or pharmacist how to stop using it gradually over a few weeks.

Things to be careful of

Be careful driving or operating machinery until you know how Nitrolingual Pumpspray affects you.

Nitrolingual Pumpspray may cause dizziness and fainting in some patients, especially when you first start to use it. Make sure you know how you react to Nitrolingual Pumpspray before you drive a car, operate machinery or do anything else which could be dangerous.

Be careful when drinking alcohol while you are using Nitrolingual Pumpspray.

If you drink alcohol while you are using Nitrolingual Pumpspray, your blood pressure may drop, making you feel dizzy or faint.

Be careful not to overdo physical activities when you first start using Nitrolingual Pumpspray.

If you use Nitrolingual Pumpspray 5 to 10 minutes before exercise, you will probably feel better and more able to participate in physical activities. However, if you overdo physical activities you may still get an attack of angina.

Get up slowly when getting out of bed or standing up if you feel lightheaded, dizzy or faint.

You may feel lightheaded or dizzy when you begin to use Nitrolingual Pumpspray or if the dose is increased. This is because your blood pressure is falling suddenly. Standing up slowly, especially when you get up from bed or chairs, will help your body get used to the change in position and blood pressure. If this problem gets worse or continues, talk to your doctor or pharmacist.

Side effects

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are using Nitrolingual Pumpspray.

Nitrolingual Pumpspray helps most people with angina, but it may have unwanted side effects in some people.

All medicines have side effects. Sometimes they are serious, most of the time they are not. You may need medical treatment if you get some of the side effects.

Do not be alarmed by this list of possible side effects. You may not experience any of them.

Common side effects:

Tell your doctor or pharmacist if you notice any of the following and they worry you:

- headache
- dizziness, weakness, feeling faint or lightheaded, especially when you stand up suddenly.

These are all mild side effects of Nitrolingual Pumpspray.

Less common side effects:

Tell your doctor or pharmacist immediately or go the casualty at your nearest hospital if you notice any of the following symptoms:

- nausea (feeling sick)
- vomiting
- severe headache
- severe dizziness or fainting
- weak or unusually fast or slow heart beat
- flushing of the face or neck
- skin rash
- weakness
- blush colour of lips, nails or palms of hand.

These are all serious side effects. You may need urgent medical attention. Serious side effects are rare.

If any of the following happen, stop taking this medicine and tell your doctor immediately, or go to Accident and Emergency at your nearest hospital:

- sudden signs of allergy such as rash, itching or hives on the skin, swelling of the face, lips, tongue or other parts of the body, shortness of breath, wheezing or trouble breathing
- swelling of the face, lips, mouth, tongue or throat which may cause difficulty in swallowing or breathing

These are very serious side effects. If you have them, you may have had a serious allergic reaction to Nitrolingual. You may need urgent medical attention or hospitalisation.

Other side effects not listed above may also occur in some patients. Tell your doctor or pharmacist if you notice anything else that is making you feel unwell.

Ask your doctor or pharmacist if there is anything in this list you don't understand.

After using it

Storage

Keep Nitrolingual Pumpspray in a cool dry place where the temperature stays below 25°C.

Do not store Nitrolingual Pumpspray or any other medicine in the bathroom or near a sink or stove. Do not leave it in the car on hot days.

Heat and dampness can destroy some medicines.

Keep Nitrolingual Pumpspray where children cannot reach it.

A locked cupboard at least one-and-a-half metres above the ground is a good place to store medicines.

Disposal

Dispose of the bottle where children cannot reach it.

There may be some solution left in the bottle which could harm them.

If your doctor tells you to stop using Nitrolingual Pumpspray, or the spray has passed its expiry date, ask your pharmacist what to do with any spray left over.

Do not open the empty container by force.

Do not spray into flames, onto red-hot surfaces or incinerate.

Product description

What it looks like

Nitrolingual Pumpspray is a metered dose pump spray. It delivers glyceryl trinitrate in the form of spray droplets. It is packaged in a plastic bottle which contains 13.9 mL of solution (200 doses).

Ingredients

Active Ingredient:

- glyceryl trinitrate 400 micrograms per metered dose spray.

Inactive Ingredients:

- fractionated coconut oil
- glyceryl caprylate/caprinate
- ethanol
- peppermint oil
- Sodium (S) - lactate solution
- (S) - Lactic acid
- Water.

Manufacturer

Nitrolingual Pumpspray is made in Germany by G. Pohl Boskamp

Supplier

Nitrolingual Pumpspray is supplied in Australia by:

sanofi-aventis australia Pty Ltd
12-24 Talavera Road
Macquarie Park NSW 2113

This leaflet was revised October 2018

Australia Register Number: AUST R 308842

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