Nitrolingual® Pumpspray

Consumer Medicine Information (CMI) summary

The full CMI on the next page has more details. If you are worried about using this medicine, speak to your doctor or pharmacist.

1. Why am I using Nitrolingual Pumpspray?

Nitrolingual Pumpspray contains the active ingredient glyceryl trinitrate. Nitrolingual Pumpspray is used to treat acute 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. For more information, see Section 1. Why am I using Nitrolingual Pumpspray? in the full CMI.

2. What should I know before I use Nitrolingual Pumpspray?

Do not use if you have ever had an allergic reaction to glyceryl trinitrate (the active ingredient) or any of the other ingredients of Nitrolingual Pumpspray listed at the end of the CMI. **Talk to your doctor or pharmacist if you have any other medical conditions, take any other medicines, or are pregnant or plan to become pregnant or are breastfeeding.** For more information, see Section 2. What should I know before I use Nitrolingual Pumpspray? in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with Nitrolingual Pumpspray and affect how it works. A list of these medicines is in Section 3 What if I am taking other medicines? in the full CMI.

4. How do I use Nitrolingual Pumpspray?

- 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.
- More instructions can be found in Section 4. How do I use Nitrolingual Pumpspray? in the full CMI.

5. What should I know while using Nitrolingual Pumpspray?

Things you should do	• Remind any doctor, dentist or pharmacist you visit that you are using Nitrolingual Pumpspray. • Tell your doctor or pharmacist if you continue to have angina attacks or if they become more frequent while you are using Nitrolingual Pumpspray.
Things you should not do	• Do not use Nitrolingual Pumpspray to treat any other complaints unless your doctor or pharmacists tell you to. • Do not suddenly stop using Nitrolingual Pumpspray if you have been using large amounts of the spray regularly.
Driving or using machines	• Be careful before you drive or use any machines or tools. Nitrolingual Pumpspray may cause dizziness and fainting in some patients, especially when you first start to use it.
Drinking alcohol	• If you drink alcohol while you are using Nitrolingual Pumpspray, your blood pressure may drop, making you feel dizzy or faint.
Looking after your medicine	• Store below 25°C.

For more information, see Section 5. What should I know while using Nitrolingual Pumpspray? in the full CMI.

6. Are there any side effects?

Less serious side effects include headache, dizziness, weakness, and feeling faint or lightheaded, especially when you stand up suddenly. Serious side effects include heart related effects such as weak or unusually fast or slow heartbeat and allergy-related effects such as sudden signs of rash, itching or hives on the skin, swelling of the face, lips, tongue, and shortness of breath. For more information, including what to do if you have any side effects, see Section 6. Are there any side effects? in the full CMI.

Nitrolingual® Pumpspray

Active ingredient: *glyceryl trinitrate*

Consumer Medicine Information (CMI)

This leaflet provides important information about using Nitrolingual Pumpspray. **You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about using Nitrolingual Pumpspray.**

Where to find information in this leaflet:

1. Why am I using Nitrolingual Pumpspray?
2. What should I know before I use Nitrolingual Pumpspray?
3. What if I am taking other medicines?
4. How do I use Nitrolingual Pumpspray?
5. What should I know while using Nitrolingual Pumpspray?
6. Are there any side effects?
7. Product details

1. Why am I using Nitrolingual Pumpspray?

Nitrolingual Pumpspray contains the active ingredient glyceryl trinitrate. Nitrolingual Pumpspray belongs to a group of medicines called nitrates. It works by widening blood vessels, letting more blood and oxygen reach the heart.

Nitrolingual Pumpspray is used to treat acute 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. 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.

2. What should I know before I use Nitrolingual Pumpspray?

Warnings

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
- you are allergic to 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

Always check the ingredients to make sure you can use this medicine.

- 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 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.

Check with 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
- you take any medicines for any other condition:
  - it may not be safe for you to use Nitrolingual Pumpspray.

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and

how to monitor for them. See additional information under Section 6. Are there any side effects?

Pregnancy and breastfeeding

Check with your doctor or pharmacist if you are pregnant or intend to become pregnant.

Talk to your doctor or pharmacist if you are breastfeeding or intend to breastfeed.

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.

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.

3. What if I am taking other medicines?

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

Some medicines may interfere with Nitrolingual Pumpspray and affect how it works.

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.
- adempas® used for pulmonary hypertension

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.

Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect Nitrolingual Pumpspray.

4. How do I use Nitrolingual Pumpspray?

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 Nitrolingual Pumpspray

- 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 Nitrolingual Pumpspray

- 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 if the opening at the bottom of the delivery tube is completely immersed in liquid. There will always be a small amount of liquid left over in the bottle. This was taken into account when the bottle was filled during its manufacture and is in addition to the 200 available doses. Make sure that you get a new spray before the old one runs out. Always keep a spare if advised to do so by your doctor or pharmacist.

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 use too much Nitrolingual Pumpspray

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.

If you think that you have used too much Nitrolingual Pumpspray, you may need urgent medical attention.

You should immediately:

- phone the Poisons Information Centre (**by calling 13 11 26**)
- contact your doctor, or
- go to the Emergency Department at your nearest hospital.

You should do this even if there are no signs of discomfort or poisoning.

5. What should I know while using Nitrolingual Pumpspray?

Things you should do

Remind any doctor, dentist or pharmacist you visit that you are using Nitrolingual Pumpspray.

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

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.

Things you should not do

- Do not use Nitrolingual Pumpspray to treat any other complaints unless your doctor or pharmacists 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 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.

Driving or using machines

Be careful before you drive or use any machines or tools 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.

Drinking alcohol

Tell your doctor or pharmacist if you drink alcohol.

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.

Looking after your medicine

- Store below 25°C.

Follow the instructions in the carton on how to take care of your medicine properly.

Store it in a cool dry place away from moisture, heat or sunlight; for example, do not store it:

- in the bathroom or near a sink, or
- in the car or on window sills.

Keep it where young children cannot reach it.

Getting rid of any unwanted medicine

- Dispose of the bottle where children cannot reach it. There may be some solution left in the bottle which could harm them.
- Do not open the empty container by force.
- Do not spray into flames, onto red-hot surfaces or incinerate.

If you no longer need to use this medicine or it is out of date, take it to any pharmacy for safe disposal.

Do not use this medicine after the expiry date.

6. Are there any side effects?

All medicines can have side effects. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention.

See the information below and, if you need to, ask your doctor or pharmacist if you have any further questions.

Less serious side effects

Less serious side effects	What to do
General • headache • dizziness • weakness • feeling faint or lightheaded, especially when you stand up suddenly	**Speak to your doctor or pharmacist if you have any of these less serious side effects and they worry you.**

Serious side effects

Serious side effects	What to do
General • weakness **Gastrointestinal** • nausea (feeling sick) • vomiting **Nervous system-related** • severe headache • severe dizziness or fainting **Skin-related** • skin rash **Heart-related** • weak or unusually fast or slow heart beat • flushing of the face or neck • bluish colour of lips, nails or palms of hand	**Call your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you notice any of these serious side effects.**

Very serious side effects

Very serious side effects	What to do
Allergy-related • 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	**Stop taking this medicine and call your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you notice any of these very serious side effects.**

Tell your doctor or pharmacist if you notice anything else that may be making you feel unwell.

Reporting side effects

After you have received medical advice for any side effects you experience, you can report side effects to the

Therapeutic Goods Administration online at www.tga.gov.au/reporting-problems. By reporting side effects, you can help provide more information on the safety of this medicine.

Always make sure you speak to your doctor or pharmacist before you decide to stop taking any of your medicines.

7. Product details

This medicine is available over-the-counter without a doctor's prescription.

What Nitrolingual Pumpspray contains

Active ingredient (main ingredient)	glyceryl trinitrate 400 micrograms per metered dose spray
Other ingredients (inactive ingredients)	fractionated coconut oil glyceryl caprylate/caprate ethanol peppermint oil sodium lactate (S) - lactic acid Purified water

Do not take this medicine if you are allergic to any of these ingredients.

What Nitrolingual Pumpspray 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).

AUST R 308842

Who distributes Nitrolingual Pumpspray

Nitrolingual Pumpspray is supplied in Australia by:

sanofi-aventis australia pty ltd

International Tower 3, Level 23

300 Barangaroo Avenue

Sydney NSW 2000

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