NITROSTAT

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 NITROSTAT?

NITROSTAT contains the active ingredient glyceryl trinitrate. NITROSTAT is used to help treat and prevent acute angina attacks (chest pain).

For more information, see Section 1. Why am I using NITROSTAT? in the full CMI.

2. What should I know before I use NITROSTAT?

Do not use if you have ever had an allergic reaction to NITROSTAT or any of the ingredients 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 NITROSTAT? in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with NITROSTAT 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 NITROSTAT?

One sublingual tablet should be dissolved under the tongue or placed between the gums and cheek at the first sign of chest pain. The dose may be repeated approximately every 5 minutes, until the chest pain is relieved.

NITROSTAT may be used 5 to 10 minutes prior to activities that might cause chest pain.

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

5. What should I know while using NITROSTAT?

Things you should do	• Remind any doctor, dentist or pharmacist you visit that you are using NITROSTAT. • Tell your doctor or pharmacist if you continue to have angina attacks or if they become more frequent while you are using NITROSTAT
Things you should not do	• You should not take NITROSTAT if you have the following conditions: very recent heart attack, severe anemia, increased pressure in the head. • You should not take Nitrostat if you are taking medicine for erectile dysfunction, like sildenafil citrate, tadalafil, or vardenafil hydrochloride.
Driving or using machines	• Be careful if you are driving or operating machinery until you know how NITROSTAT affects you. NITROSTAT may lower your blood pressure and make you feel dizzy or lightheaded.
Drinking alcohol	• Do not consume alcohol while taking NITROSTAT, as this can lower your blood pressure.
Looking after your medicine	• Store in a cool dry place away from moisture, heat or sunlight below 25°C. • Keep your tablets in the original package until it is time to take them.

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

6. Are there any side effects?

Common side effects include vertigo (a major symptom of balance disorder), dizziness, weakness, heart palpitations (unusual awareness of the heartbeat), low blood pressure upon rising from a seated position, nausea and vomiting, sweating, paleness, fainting, flushing (warm or red condition of your skin)

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.

NITROSTAT

Active ingredient(s): *Glyceryl trinitrate*

Consumer Medicine Information (CMI)

This leaflet provides important information about using NITROSTAT. **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 NITROSTAT.**

Where to find information in this leaflet:

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

1. Why am I using NITROSTAT?

NITROSTAT contains the active glyceryl trinitrate.
NITROSTAT belongs to a group of medicines called nitrates and works by widening blood vessels.

The glyceryl trinitrate causes the blood vessels to relax and increases the supply of blood and oxygen to the heart reducing the likeliness of having an angina attack.

NITROSTAT is used to treat acute angina.

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

Angina is a pain or discomfort that keeps coming back when part of your heart does not get enough blood. Angina feels like a pressing or squeezing pain, usually in your chest under the breastbone. Sometimes you can feel it in your shoulders, arms, neck, jaws, or back.

2. What should I know before I use NITROSTAT?

Warnings

Do not use NITROSTAT if:

- you are allergic to glyceryl trinitrate (the active ingredient), or any of the ingredients listed at the end of this leaflet.
- you are allergic to any medicine or food containing nitrates or nitrites.
- You are taking medicine for erectile dysfunction, like sildenafil citrate, tadalafil, or vardenafil hydrochloride, as this may lead to extreme lowering of your blood pressure.
- you take medicines called guanylate cyclase stimulators, a medicine that treats pulmonary arterial hypertension and chronic-thromboembolic pulmonary hypertension.

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

You should not take NITROSTAT if you have the following conditions:

- very recent heart attack
- severe anemia
- increased pressure in the head

Check with your doctor or pharmacist if you:

- have any other medical conditions including
  - low blood pressure
  - heart problems or blood vessel disorder other than angina
- take any medicines for any other condition

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.

The safety of NITROSTAT in pregnancy has not been established.

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

It is unknown whether NITROSTAT passes into breast milk.

Use in Children

NITROSTAT 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 NITROSTAT.

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 NITROSTAT and affect how it works.

- medicine which expand the blood vessels
- medicine which lower blood pressure
- medicine used to treat impaired sexual function

- medicine used to treat high blood pressure in the pulmonary artery
- medications used to treat heart failure and pulmonary arterial hypertension (PAH), a condition of high blood pressure
- medicine which help to reduce the amount of excess fluid in the body by increasing the amount of urine produced
- medicine which dissolves clots that have formed in blood vessels. It's used to treat stroke, heart attack and blood clots in the lungs
- some medicine for mental conditions
- some medicine used to treat depression.
- some medicine used to treat migraine headaches.
- Heparin and aspirin, used to thin the blood.
- Adempas® (riociguat) used for pulmonary hypertension

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

If you have been prescribed a phosphodiesterase 5 inhibitor, medicine 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 NITROSTAT.

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

4. How do I use NITROSTAT?

How much to take

- Your doctor or pharmacist will tell you how much NITROSTAT to take.
- Use the exact amount your doctor or pharmacist tells you to.
- One sublingual tablet should be dissolved under the tongue or between the gums and cheek at the first sign of chest pain. Do not chew, crush or swallow the tablet.
- If the pain persists after five minutes, take another tablet.
- If the pain persists after a total of 3 tablets in a 15-minute period, or is different than you typically experience, call your doctor or seek emergency help.
- Follow the instructions provided with the medicine.
- Do not exceed the recommended dosage.

When to take NITROSTAT

- Your doctor or pharmacist will tell you how often you should take NITROSTAT.
- NITROSTAT 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.
- NITROSTAT 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 NITROSTAT 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 take NITROSTAT

- Sit down and rest before taking NITROSTAT.
- The sublingual tablet should be dissolved under the tongue or between the gums and cheek at the first sign of chest pain. **Do not chew, crush or swallow the tablet.**

If you use too much NITROSTAT

If you have taken too much NITROSTAT, you may suffer severe headaches. Your skin may become flushed or clammy, cold sweats, you may have trouble seeing or you may feel flushed, nauseous (sick), diarrhea, dizzy, lightheaded, shortness of breath or faint. Your heart may also beat faster or slower than usual.

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

You should immediately:

- phone the Poisons Information Centre (Australia telephone 13 11 26) for advice, or
- 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 NITROSTAT?

Things you should do

Remind any doctor, dentist or pharmacist you visit that you are taking NITROSTAT.

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

Take NITROSTAT 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 NITROSTAT.

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.

NITROSTAT may produce a burning or tingling sensation when dissolving under your tongue.

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

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 continues or gets worse, talk to your doctor.

Tell your doctor or pharmacist immediately if you become pregnant while using NITROSTAT.

Tell your doctor or pharmacist immediately if you are trying to become pregnant while using NITROSTAT.

Things you should not do

- Do not take NITROSTAT 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.

Driving or using machines

Be careful before you drive or use any machines or tools until you know how NITROSTAT affects you.

NITROSTAT may cause dizziness and fainting in some patients, especially when you first start to use it. Make sure you know how you react to NITROSTAT 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.

Do not consume alcohol while taking NITROSTAT, as this can lower your blood pressure, making you feel dizzy or faint.

Looking after your medicine

- Store below 25°C.
- Keep your tablets in the original container until it is time to take them.

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

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 • Sweating that does not occur due to heat but follows a sudden chill • 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..**

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 heartbeat • increase pressing or squeezing pain, usually in your chest under the breastbone, shoulders, arms, neck, jaws, or back.	**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.

Other side effects not listed here may occur in some people.

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.

7. Product details

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

What NITROSTAT contains

Active ingredient (main ingredient)	glyceryl trinitrate
Other ingredients (inactive ingredients)	Lactose monohydrate, glyceryl monostearate, pregelatinised starch, calcium stearate, and colloidal anhydrous silica.
Potential allergens	Lactose and sulfites

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

What NITROSTAT looks like

NITROSTAT 300 micrograms sublingual tablets:

Small, round, white, tablet debossed with “3” on one side and “N” on the other side.

AUST R 438870

NITROSTAT 400 micrograms sublingual tablets:

Small, round, white, tablet debossed with “4” on one side and “N” on the other side.

AUST R 43 8851

300 micrograms are available in a glass bottle with 100 tablets.

400 micrograms are available in 4 glass bottles with 25 tablets each.

Who distributes NITROSTAT

Viatris Pty Ltd

Level 1, 30 The Bond

30-34 Hickson Road

Millers Point NSW 2000

www.viatris.com.au

Phone: 1800 274 276

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