

Package leaflet: Information for the user

Glyceryl Trinitrate Spray

400 micrograms per metered dose,
Sublingual spray
glyceryl trinitrate

Read all of this leaflet carefully before you start using this medicine because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What Glyceryl Trinitrate Spray is and what it is used for
2. What you need to know before you use Glyceryl Trinitrate Spray
3. How to use Glyceryl Trinitrate Spray
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6. Contents of the pack and other information

1. WHAT GLYCERYL TRINITRATE SPRAY IS AND WHAT IT IS USED FOR

Your medicine is called Glyceryl Trinitrate Spray. It will be referred to throughout this leaflet as GTN Spray.

It is a sublingual (under the tongue) aerosol spray that contains the active ingredient glyceryl trinitrate. Glyceryl trinitrate belongs to a group of medicines called nitrates that relax the muscle walls of the blood vessels and reduce the workload of the heart.

GTN Spray is used to treat angina at the onset of an attack. It is also used for the prevention of angina, which can be brought on from physical effort, emotional stress, and exposure to cold, etc.

2. WHAT YOU NEED TO KNOW BEFORE YOU USE GLYCERYL TRINITRATE SPRAY

Do not use GTN Spray:

- If you are **allergic** to glyceryl trinitrate or any of the other ingredients of this medicine (listed in section 6).
- If you have severe **low blood pressure**.
- If you have **shock** caused by low blood pressure.
- If you have severe **anaemia**.
- If you have **constrictive pericarditis** (a heart condition).
- If you have an extremely **low heart rate**.
- If you have **glucose-6-phosphate-dehydrogenase deficiency** (an inherited enzyme deficiency, mainly affecting men).
- If you have a **brain trauma or cerebral haemorrhage** (brain or head injury, including bleeding).
- If you have **narrowing of the heart valves or arteries** or angina caused by a disease of the heart muscle.
- If you have **circulatory collapse** (a failure of blood circulation).
- If you have toxic **pulmonary oedema** (lung swelling/ fluid)
- If you have **cardiogenic shock** (a serious heart condition caused by very low blood pressure, which may result in the following symptoms: dizziness and lightheadedness, fast pulse rate, white skin, sweating, restlessness or loss of consciousness).

Warnings and precautions

Talk to your doctor before using GTN Spray if any of the following apply to you:

- Fluid around the heart (pericardial tamponade).
- Low filling pressures (e.g. acute myocardial infarction).
- Problems controlling your blood pressure.
- Any disease that increases pressure on the brain.
- Glaucoma (a condition in which the pressure in the eye may be high).
- Liver or kidney problems.
- An underactive thyroid gland.

Please consult your doctor, even if these statements were applicable to you at any time in the past. You may need to be more closely supervised during treatment.

Children and adolescents

Do not give this medicine to children and adolescents under 18 years.

Other medicines and GTN Spray

Tell your doctor if you are taking, have recently taken or might take any other medicines.

Do not use GTN Spray if you are taking:

- **Riociguat**, used to treat pulmonary hypertension.
- **Sildenafil, tadalafil, vardenafil** or other similar phospho-diesterase inhibitors used to treat male erectile dysfunction (impotence).

Talk to your doctor before using GTN Spray if you are taking or have recently taken any of the following:

- Medicines to treat blood pressure or heart problems, such as vasodilators, antihypertensives, betablockers and calcium channel blockers.
- Tricyclic anti-depressants or neuroleptics, used to treat mental health conditions.
- Diuretics (water tablets to increase amount of urine produced).
- Dihydroergotamine, used to treat migraine headaches.
- Heparin, a blood thinner used to prevent blood clots. Your doctor will need to monitor you more closely.
- Organic nitrates (other acute angina treatments).

GTN Spray with alcohol

Be careful about drinking alcohol as GTN Spray may affect you more than usual. Both alcohol and GTN Spray may lower your blood pressure and slow down your reactions.

Pregnancy and breast-feeding

If you are, or think you might be pregnant, ask your doctor for advice before taking this medicine. GTN Spray should not be used if you are breastfeeding.

Driving and using machines

Your reactions may slow down. Therefore, you should avoid driving and using machinery whilst using GTN Spray.

GTN Spray contains ethanol

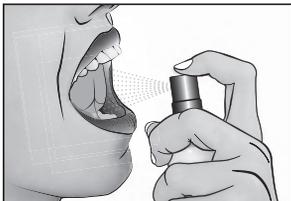
This medicine contains 7.5 mg of alcohol (ethanol) in each spray. The amount in one spray of this medicine is equivalent to less than 1 ml beer or 1 ml wine. The small amount of alcohol in this medicine will not have any noticeable effects.

Continuous use warning

Continuous use of GTN Spray and other nitrates may reduce effectiveness at relieving your symptoms, so high continuous doses should be avoided.

3. HOW TO USE GLYCERYL TRINITRATE SPRAY

1. GTN Spray is not recommended for children.
2. Always use this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.
3. Learn how to use GTN Spray before the onset of an angina attack, as you may need to use it in a hurry, or in the dark. Familiarise yourself with the spray button, which has a finger rest to help you direct the spray.
4. Keep a spare handy at all times as it can be difficult to tell how many doses are left in the canister.
5. **Do not use GTN Spray if you are near a naked flame, e.g. a cigarette.**



6. **Before using GTN Spray for the first time**, check that the spray is working by pressing the spray button a few times until it produces a fine mist of liquid. Practice aiming the spray onto a tissue or similar item so that you will be able to aim it correctly under the tongue when you need to use it. **If you do not need to use GTN spray very often**, remember to check the spray regularly to see that it still works properly.
7. At the onset of an attack, or to prevent an imminent attack:
 - Sit down.
 - Hold the canister upright and near your mouth.
 - **Hold your breath.**
 - Aim the **spray under your tongue.**
 - Press down the button firmly, once only.
 - **Close your mouth** immediately.
 - **Do not inhale** the spray.
8. **The usual dose is one or two sprays.** No more than three doses are recommended at any one time.
9. After using GTN Spray, rest for a while. When you stand up, rise slowly, as you may feel faint.

If you use more GTN Spray than you should:

Special treatment is not normally required. Overdose symptoms are usually the same as the stated side effects. Some people may experience a reaction similar to shock, with nausea, weakness and sweating. If you feel faint sit down and raise your legs. Contact your doctor if your symptoms do not improve. Rarely a bluish colour to lips/fingers may occur (cyanosis or methaemoglobinaemia). If this happens contact your doctor immediately.

4. POSSIBLE SIDE EFFECTS

Like all medicines, this medicine can cause side effects, although not everyone gets them.

If you experience one of the following rare serious side effects (may affect up to 1 in 1,000 people unless specified), **stop taking GTN Spray immediately and consult your doctor:**

- An allergic skin reaction (with or without rash).
- Tongue blistering (may affect up to 1 in 100 people).
- Fainting.
- A severe fall in blood pressure on standing up.
- Worsening of the original angina symptoms.
- Failure of the blood circulation (decrease in blood pressure, may be followed by loss of consciousness and collapse)
- Transient hypoxaemia (deprived oxygen supply) (bluish colouration of the lips, hands or feet, may be followed by loss of consciousness)
- Patients with coronary heart disease may experience a restriction in blood supply.

Continuous use may result in a tolerance to GTN Spray, reducing its effectiveness. If symptoms are not relieved, medical advice should be sought immediately.

Other known side effects are:

Very common (may affect more than 1 in 10 people)	Headache
Common (may affect up to 1 in 10 people)	Vertigo (spinning sensation), dizziness, nausea, facial flushing, weakness
Uncommon (may affect up to 1 in 100 people)	Burning sensation, stinging sensation
Rare (may affect up to 1 in 1,000 people)	Severe fall in blood pressure, heart rhythm change
Very rare (may affect up to 1 in 10,000 people)	Flaking or peeling skin

Reporting of side effects

If you get any side effects, talk to your doctor. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme Website: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store.

By reporting side effects, you can help provide more information on the safety of this medicine.

5. HOW TO STORE GLYCERYL TRINITRATE SPRAY

- **Keep this medicine out of the sight and reach of children.**
- Do not use this medicine after the expiry date which is stated on the label and carton after EXP. The expiry date refers to the last day of that month.
- Do not store above 25°C. Do not refrigerate or freeze.
- GTN Spray is an aerosol spray and contains a pressurised liquid. Do not expose to temperatures higher than 50°C. Do not pierce the canister, even when empty. Do not spray at or use near a naked flame.
- Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. CONTENTS OF THE PACK AND OTHER INFORMATION

What GTN Spray contains:

- The active substance is glyceryl trinitrate. Each spray contains 400 micrograms of glyceryl trinitrate.
- The other ingredients are peppermint oil, ethanol and 1,1,1,2 tetrafluoroethane (the propellant).

What GTN Spray looks like and contents of the pack

- GTN Spray is a colourless spray presented in an aluminium container (canister), with a metered dose spray nozzle, and a cap.
- Each container contains enough product for 180 or 200 sprays.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder: Ayrton Saunders Ltd., 9 Arkwright Road, Astmoor Industrial Estate, Runcorn, Cheshire, WA7 1NU, United Kingdom.

Manufacturer: Pharmaserve (North West) Ltd, 9 Arkwright Road, Astmoor Industrial Estate, Runcorn, Cheshire, WA7 1NU, United Kingdom.

For information in large print, audio CD or braille please contact the Marketing Authorisation Holder.

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