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**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 and talk to your doctor:
- 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, weak skin, sweating, restlessness or loss of consciousness).

Do not use if you are taking:
- riociguat to treat pulmonary hypertension
- sildenafil, tadalafil, vardenafil or other similar phosphodiesterase inhibitors used to treat male erectile dysfunction (impotence).

**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.

**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.
- Triicyclic 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 breast-feeding.

**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 product contains small amounts of ethanol (alcohol), less than 100mg per spray.

**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 pump 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 methaemoglobinemia). 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.
- Transient hypoxaemia (deprived oxygen supply).
- 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 national reporting system listed in Yellow Card Scheme Website: www.mhra.gov.uk/yellowcard. 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 carton and the canister base 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, and do not pierce the canister, even when empty.
- 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 ingredient is glyceryl trinitrate. Each spray of product 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 a printed aluminium canister, with a metered dose spray nozzle, and a cap.
- Each canister contains enough product for 180 or 200 sprays.

Marketing Authorisation Holder and Manufacturer
MA 16431/0018
Marketing Authorisation Holder: Ayrton Saunders Ltd., 9 Arkwright Road, Astmoor Industrial Estate, Runcorn, Cheshire, WA7 1NU, UK.
Manufacturer: Pharmasol Limited, North Way, Andover, SP10 5AZ, UK.
For information in large print, audio CD or braille please contact the Marketing Authorisation Holder.
This leaflet was last revised in April 2017.
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