

Package leaflet: Information for the user

Glytrin

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 Glytrin is and what it is used for
2. What you need to know before you use Glytrin
3. How to use Glytrin
4. Possible side effects
5. How to store Glytrin
6. Contents of the pack and other information

1. WHAT GLYTRIN IS AND WHAT IT IS USED FOR

Your medicine is called Glytrin.

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.

Glytrin 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, exposure to cold, etc.

2. WHAT YOU NEED TO KNOW BEFORE YOU USE GLYTRIN

Do not use Glytrin 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).
- Have severe **low blood pressure**.
- Have **shock** caused by low blood pressure.
- Have severe **anaemia**.
- Have **constrictive pericarditis** (a heart condition).
- Have an extremely **low heart rate**.
- Have a **brain trauma or cerebral haemorrhage** (brain or head injury, including bleeding).
- Have **narrowing of the heart valves or arteries** or angina caused by a disease of the heart muscle.
- Have **circulatory collapse** (a failure of blood circulation).
- Have toxic **pulmonary oedema** (lung swelling/fluid).
- 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).

Do not use Glytrin 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 Glytrin 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 Glytrin

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

Do not use Glytrin if you are taking:

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

Talk to your doctor before using Glytrin 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).

Glytrin with alcohol

Be careful about drinking alcohol as Glytrin may affect you more than usual. Both alcohol and Glytrin 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. Glytrin 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 Glytrin.

Glytrin 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 Glytrin and other nitrates may reduce effectiveness at relieving your symptoms, so high continuous doses should be avoided.

3. HOW TO USE GLYTRIN

1. Glytrin 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 Glytrin 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 Glytrin if you are near a naked flame, e.g. a cigarette.**



6. To use Glytrin

- 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.
7. At the onset of an attack, the recommended dose is one or two sprays under your tongue. If symptoms do not resolve, you can repeat this at 5-minute intervals for a maximum of three sprays in total. If, after that, your symptoms have still not resolved, please seek immediate medical attention. For the prevention of an attack, the recommended dose is one or two sprays 2 to 3 minutes prior to activity likely to cause angina.
 8. After using Glytrin, rest for a while. When you stand up, rise slowly, as you may feel faint.

If you use more Glytrin 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 Glytrin 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 Glytrin, 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, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly to:

HPRA Pharmacovigilance

Website: www.hpra.ie

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

5. HOW TO STORE GLYTRIN

- **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.
- Warning. Pressurised container. May burst if heated.
- Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking. Do not pierce or burn, even after use.
- Protect from sunlight. Do not expose to temperatures exceeding 50°C.
- Do not store above 25°C. Do not refrigerate or freeze.
- 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 Glytrin contains

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

What Glytrin looks like and contents of the pack

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

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder:

Evolan Pharma AB, Box 120, 182 12 Danderyd, Sweden

Manufacturer:

Pharmaserve (North West) Ltd, 9 Arkwright Road, Astmoor Industrial Estate, Runcorn, Cheshire, WA7 1NU, UK.

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

This leaflet was last revised in