

PACKAGE LEAFLET

Package leaflet: Information for the user

Nitrolingual Pumpspray 400 micrograms per metered dose, sublingual spray

glyceryl trinitrate

Read all of this leaflet carefully before you start taking 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 or nurse.
- 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, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet:

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

1. What Nitrolingual is and what it is used for

Nitrolingual is a sublingual spray which you use under your tongue. The active ingredient is called glyceryl trinitrate or GTN for short. GTN is one of a group of medicines called ‘nitrates’. These relax the muscles around the blood vessels and make it easier for the heart to do its work.

Nitrolingual helps stop the pain of angina (pain in your chest, arms or neck especially when you exert yourself). You can also use the medicine immediately before doing things which you know will cause you angina pain.

2. What you need to know before you take Nitrolingual

Do not take Nitrolingual

- if you are allergic (hypersensitive) to nitrates or any of the other ingredients of Nitrolingual (see list of ingredients in section 6). An allergic reaction may include rash, itching, difficulty breathing or swelling of the face, lips, throat or tongue.
- if you are **very ill because of very low blood pressure, severe blood loss, a stroke, bleeding in the brain, a severe head injury or severe anaemia**
- if you have certain **unusual heart conditions** (such as acute circulatory shock, including hypovolaemic shock, uncontrolled cardiogenic shock, (‘shock’ in these cases is where insufficient blood flow reaches the body’s tissues), severe mitral stenosis or hypertrophic obstructive cardiomyopathy), which your doctor will have told you about
- if you are taking sildenafil or similar products (e. g., vardenafil, tadalafil) for the treatment of erectile dysfunction or hypertension of arterial lung vessels. If you take these products and Nitrolingual, a severe and possibly dangerous fall in blood pressure can occur. This would result in collapse, unconsciousness and could be fatal.

Warnings and precautions

Talk to your doctor or pharmacist or nurse before taking Nitrolingual

- if you have an eye condition called incipient glaucoma
- if taking Nitrolingual®, while the spray does not stop the pain; or if the spray usually works, but this time the pain lasts longer (half an hour or more), or feels different or worse than usual
- if you have mitral stenosis (a narrowing of the opening to the heart mitral valve)
- if you feel dizzy when you sit or stand upright suddenly

- if you have cerebrovascular disease (brain disorders relating to disease of the blood vessels supplying the brain)
- if you have pericardial tamponade (compression of the heart caused by blood or fluid accumulation in the space between the heart muscle and the outer covering of the heart)
- if you have constrictive pericarditis (inflammation and swelling of the covering of the heart)
- if you have blood oxygen in lung disease or pulmonary heart disease (enlargement of the right ventricle of the heart)
- if you have had a heart attack
- if you have left ventricular hypertrophy (thickening of the muscle of the left ventricle of the heart) associated with aortic stenosis (narrowing of the opening of the aortic heart valve)
- if you have moderate to severe valvular aortic stenosis (narrowing of the opening of the aortic heart valve)

Use in children

No data are available on the use of Nitrolingual® in children.

Other medicines and Nitrolingual

Tell your doctor or pharmacist if you are taking or have recently taken or might take any other medicines, including medicines obtained without a prescription. This is important as using more than one medicine at the same time can strengthen or weaken the effect of the medicines. Your doctor may need to take special care or change the dose. This is especially important for:

- medicines for the treatment of erectile dysfunction or hypertension of arterial lung vessels (see ‘Do not take Nitrolingual®’)
- other medicines which can lower blood pressure, such as beta-blockers (used to treat heart conditions), calcium channel blockers (used to treat chest pain or high blood pressure) and neuroleptics (used to treat schizophrenia, psychosis), vasodilators (widen blood vessels), anti-hypertensives, diuretics (water tablets), tricyclic antidepressants, sapropterin (used in the treatment of phenylketonuria (PKU), an inherited condition where protein from the diet cannot be processed correctly)
- anti-blood-clotting drugs such as heparin
- N-acetyl-cysteine (used in the treatment of paracetamol overdose and as a mucolytic agent)
- dihydroergotamine (a drug used for the treatment of migraine). The levels of dihydroergotamine in your blood may increase if you take Nitrolingual® together with such medicines. As a result, dihydroergotamine may increase your blood pressure more than usual.

If you use Nitrolingual® very often or if you regularly use other nitrates, the pain relief you receive may be less.

Nitrolingual with alcohol

If you drink alcohol before using Nitrolingual®, you may feel dizzy or faint due to low blood pressure.

Pregnancy and breast-feeding

Tell your doctor if you become pregnant while you are taking Nitrolingual®. You should use Nitrolingual only after discussing with your doctor the potential benefits to you versus any potential risks to your unborn child.

It is not known whether glyceryl trinitrate passes into human breast milk. You should ask your doctor for advice if you are breast-feeding. There is no sign of a harmful effect with respect to fertility in animal studies, however there is no similar information for humans.

Driving and using machines

You should wait at least five minutes after using the spray before driving or operating machinery. If you feel faint, dizzy or unwell after using Nitrolingual®, wait until you feel better before driving or operating machinery.

Nitrolingual contains ethanol

This medicinal product contains small amounts of ethanol (alcohol); less than 10 mg per metered dose (puff).

3. How to take Nitrolingual

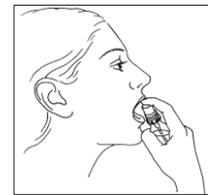
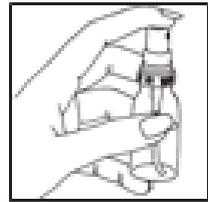
Dosage

Always take this medicine exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure. The spray is meant for use under your tongue and is not meant to be inhaled. The recommended dose is one or two puffs under your tongue. If symptoms do not resolve, you can repeat this at 5 minute intervals for a maximum of two more times, for a total of three doses. If, after that, your symptoms have still not resolved, please seek immediate medical attention. The spray should work quickly and last about half an hour.

Method of administration

Before you use a new bottle of Nitrolingual, spray the first puff into the air to get the pump working properly. You must also do this if you have not used the pump for a week or more. Get used to the feel of the grooved button in case you need to use the pump in the dark.

1. Rest or sit quietly, as you may feel faint or dizzy otherwise, particularly if you are elderly.
2. Hold the bottle upright with your finger on the button. You don't need to shake the bottle.
3. Open your mouth and put the bottle next to your chin (see picture).
4. Press the button firmly so that the puff of medicine goes under your tongue. Close your mouth.
5. Do not breathe in while you are taking the puff of medicine.



Keep the spray with you at all times. Through the side of the bottle you can see how much spray you have left. Make sure that you get a new spray before the old one runs out. Always keep a spare.

Talk with your doctor about how long you should keep taking Nitrolingual.

If you take more Nitrolingual than you should

If you take too many puffs you may notice more severe and pronounced side effects (see section 4), for example, you may get a bad headache, blurred vision, feel flushed or feel that your heart is beating more slowly. You may also feel faint, sweaty, breathless, weak, restless and feel sick or be sick, or notice a bluish tinge to your lips. If any of these effects persist contact your doctor or pharmacist.

If you forget to take Nitrolingual

Do not take a double dose to make up for a forgotten dose.

If you stop taking Nitrolingual

Do not stop taking Nitrolingual® without the advice of your doctor.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist or nurse.

4. Possible side effects

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

The following side effects have been reported:

Very common side effects (may affect more than 1 in 10 people):

- headache

Common side effects (may affect up to 1 in 10 people):

- decreased blood pressure, which can also occur on standing up;
- weakness;
- dizziness;
- drowsiness;
- increased heart rate

Uncommon side effects (may affect up to 1 in 100 people):

- fainting;

- worsened angina symptoms;
- slowing of the heart rate;
- bluish colouration of the skin;
- facial flushing;
- circulatory collapse (failure of the blood circulation);
- nausea;
- vomiting;
- allergic skin rash

Very rare side effects (may affect up to 1 in 10,000 people):

- cerebral ischaemia (decreased blood flow to the brain);
- methaemoglobinaemia (a disorder of the red blood cells);
- restlessness;
- difficulty breathing;
- skin rash

Not known (frequency cannot be estimated from the available data):

- tongue swelling (due to an allergic reaction)

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 via HPRAs 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 Nitrolingual

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 bottle after 'EXP'. The expiry date refers to the last day of that month.

Do not store Nitrolingual® above 25 °C.

Do not throw any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help to protect the environment.

6. Contents of the pack and other information

What Nitrolingual contains

The active substance is glyceryl trinitrate (GTN). Each puff of spray contains 400 micrograms of GTN.

The other excipients are medium-chain triglycerides, ethanol anhydrous (alcohol), medium-chain partial glycerides, peppermint oil, sodium (*S*)-lactate solution and (*S*)-lactic acid.

What Nitrolingual looks like and contents of the pack

Glass bottle which may be plastic-coated and pre-printed or labelled, fitted with a metering pump. Each bottle contains 6.3 g, 12.1 g, 13.2 g or 15.4 g solution (equivalent to about 75, 180, 200 or 250 doses). Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

G. Pohl-Boskamp GmbH & Co. KG

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For any further information about this medicine, please contact the UK distributor:

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