

**PATIENT INFORMATION LEAFLET**  
**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 any of the 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, While taking Nitrolingual, tell your doctor if 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 low 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 if you').
- 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), antihypertensives, 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 frequency of side effects is classified into the following categories:

Very common: may affect more than 1 in 10 people

Common: may affect up to 1 in 10 people

Uncommon: may affect up to 1 in 100 people

Rare: may affect up to 1 in 1,000 people

Very rare: may affect up to 1 in 10,000 people

Not known: frequency cannot be estimated from the available data.

The following side effects have been reported:

Very common: headache

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

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

Not known: tongue swelling (due to an allergic reaction)

### **Reporting of side effects**

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the national reporting system: IMB Pharmacovigilance, Earlsfort Terrace, IRL - Dublin 2  
Tel: +353 1 6764971 Fax: +353 1 6762517

Website: [www.imb.ie](http://www.imb.ie)

e-mail: [imbpharmacovigilance@imb.ie](mailto:imbpharmacovigilance@imb.ie)

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

## **5. HOW TO STORE NITROLINGUAL**

Keep out of the sight and reach of children.

Do not use the spray after the 'expiry date' which is stated on the carton and bottle over-labels as 'Exp'.

The expiry date refers to the last day of that month.

Expiry date refers to the last day of the month.

Do not store above 25°C.

## **6. FURTHER INFORMATION**

### **What Nitrolingual contains**

The active ingredient is called glyceryl trinitrate or GTN for short. Each puff of spray contains 400micrograms of GTN. Also contains coconut oil, ethanol, medium-chain partial glycerides, and peppermint oil.

### **What Nitrolingual looks like and contents of the pack**

Nitrolingual is a sublingual spray which you use under your tongue.

This medicinal product contains small amount of ethanol, less than 100mg per metered dose.

Each bottle contains 11.2g of solution (equivalent to about 200 doses).

**Manufactured by:** G.Pohl-Boskamp GmbH & Co., Hohenlockstedt, Germany.

**Procured from within the EU & repackaged by**

**PPA holder:** B&S Healthcare, Unit 4, Bradfield Road, Ruislip, Middlesex, HA4 ONU, UK

**Nitrolingual Pumpspray 400 micrograms per metered dose, sublingual spray**

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