PACKAGE LEAFLET: INFORMATION FOR THE USER

Nitronal 1 mg/ml solution for infusion

glyceryl trinitrate

Read all of this leaflet carefully before you start taking this medicine.
- 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. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

In this leaflet:

1. WHAT NITRONAL IS AND WHAT IT IS USED FOR

Nitronal contains glyceryl trinitrate (GTN). GTN belongs to a group of medicines called nitrates, which relax the muscle around blood vessels and make the heart's work easier.
Nitronal® is a medicine which is only used in hospitals. It is used in three conditions:
- in heart failure
- in angina
- to lower the blood pressure during surgery.

All patients given Nitronal are monitored very carefully.

2. BEFORE YOU TAKE NITRONAL

Do not take Nitronal if you
- are allergic (hypersensitive) to nitrates or any of the other ingredients of Nitronal (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.
- are taking certain drugs (phosphodiesterase-5-inhibitors,e.g. sildenafil or vardenafil, or soluble guanylate cyclase stimulators, e.g. riociguat) for the treatment of erectile dysfunction or hypertension of arterial lung vessels. If you take these products and Nitronal®, a severe and possibly dangerous fall in blood pressure can occur. This would result in collapse, unconsciousness and could be fatal.
- are suffering from:
- **acute circulatory failure**
- **shock**
- **low blood pressure**
- **a condition called cardiogenic shock – a condition which prevents the heart from beating correctly, unless medical procedures or other medicines have been taken to correct the heart rhythm.**
- **toxic pulmonary oedema. This is where there is fluid on the lungs caused e.g. by smoke inhalation. Use of Nitronal® can worsen this condition.**
- **severe anaemia**
- **bleeding in the brain or where there is evidence of increased pressure in the brain**
- **low blood oxygen**
- **severe blood loss**
- a certain heart disease called **hypertrophic obstructive cardiomyopathy**

- very **low heart rate**

Nitronal is not intended for use in children.
Take special care with Nitronal
Before treatment with Nitronal, tell your doctor if you have any of these medical conditions:
- severe liver disease
- kidney disease
- low body temperature
- underactive thyroid
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- constrictive pericarditis - where the heart muscle becomes inflamed and is unable to beat efficiently
- cardiac tamponade - where there is fluid in a sac that surrounds the heart, which affects it beating correctly
- heart valve problems
- low filling pressure in the heart, resulting from conditions including acute myocardial infarction (heart attack) and heart failure
- regular dizzy spells when standing up
- low blood volume. You may need to receive additional fluids via a "drip" before you are given Nitronal.
- cerebrovascular disease since symptoms may be provoked by hypotension
- left ventricular hypertrophy (thickening of the wall of the heart's main pumping chamber) associated with aortic stenosis (left ventricular heart valve narrowing), as this might theoretically compromise myocardial blood supply

Taking other medicines
Please tell your doctor or pharmacist if you are taking or have recently taken 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:
- drugs which lower blood pressure as well as beta blockers and calcium antagonists.
- previous treatment with other heart drugs containing nitrates such as isosorbide mononitrate and isosorbide dinitrate – your doctor may need to increase the dose of Nitronal®
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- certain antidepressants (tricyclics) and antipsychotic medicines (e.g. chlorpromazine).
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- medicines for the treatment of erectile dysfunction or hypertension of arterial lung vessels (phosphodiesterase-5-inhibitor, soluble guanylate cyclase stimulator; see also 'Do not take Nitronal if you').
- medicines containing sapropterin used by people with phenylketonuria (PKU).
- treatments containing dihydroergotamine.

N-acetylcysteine may potentiate the vasodilative effects of glyceryl trinitrate.

Also if you have had any alcoholic drinks or medicines which contain alcohol, this can increase the side effects of Nitronal.

Pregnancy and breast-feeding
Tell your doctor if you are pregnant. You should only be administered Nitronal® 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

Nitronal may affect the ability to drive or operate machinery. Do not drive or operate any tools or machines until you know how Nitronal® affects you.

Important information about some of the ingredients of Nitronal
Nitronal contains 49 milligrams of **glucose monohydrate** per millilitre (ml). You should take this into account if you have diabetes mellitus.

3. HOW TO TAKE NITRONAL

Dosage
Nitronal will be given to you in hospital.
Nitronal is always given slowly into the blood stream (intravenous administration). The usual dose for adults and the elderly depends on the condition:
Heart failure: 10 to 100 micrograms per minute
Angina: Initially 10 to 15 micrograms per minute, increasing until the angina is relieved
Lowering blood pressure during surgery: 25 to 200 micrograms per minute

If you take more Nitronal than you should
Overdose is highly unlikely, as Nitronal® will be given to you in hospital, but you might experience vomiting, restlessness, low blood pressure, fainting, a bluish tinge to the skin, coldness of the skin, difficulty breathing, slow heart rate, psychosis or methaemoglobinaemia (a blood disorder), nausea, diarrhoea or weakness. Your doctor would know how to treat you for overdose.
If you have any further questions on the use of this product, ask your doctor or pharmacist.

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
Very rare: cerebral ischaemia (decreased blood flow to the brain); methaemoglobinaemia (a disorder of the red blood cells); restlessness; difficulty breathing; dermatitis, skin rash
Not known: tolerance to the effect of the drug; increased sweating

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 the Yellow Card Scheme at: 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 NITRONAL

Keep out of the reach and sight of children.
Your doctor and hospital pharmacist are responsible for the correct storage, use and disposal of Nitronal. Nitronal should be stored unopened: Do not store above 25 °C. Do not freeze. Keep the ampoules and vial in the outer carton and use before the expiry date printed on the ampoule or vial and

carton. The expiry date refers to the last day of that month. The diluted solution, which should be used as soon as possible, is stable in the recommended infusion system for up to 24 hours. Nitronal is for single dose use only. Discard any unused contents.

6. FURTHER INFORMATION

What Nitronal contains

The active substance is glyceryl trinitrate (GTN). Nitronal contains 1 milligram (mg) per millilitre (ml) of GTN. Each 5 ml ampoule contains 5 mg of GTN, each 10 ml ampoule contains 10 mg GTN, each 25 ml ampoule contains 25 mg GTN and each 50 ml vial contains 50 mg of GTN. The other ingredients are glucose monohydrate, water for injections, and dilute hydrochloric acid.

What Nitronal looks like and contents of the pack

Nitronal is a sterile, colourless solution for infusion.
Nitronal is available as cartons of 10 amber glass ampoules containing 5 ml, 10 ml or 25 ml of solution, or single clear glass vials containing 50 ml of solution.
Not all pack sizes may be marketed.

Marketing Authorisation Holder
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