



Package leaflet: Information for the patient
Nicardipine 10 mg/10 ml solution for injection
Nicardipine hydrochloride

Read all of this leaflet carefully before you are given 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 nurse.
- If you get any side effects, talk to your doctor or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

The name of your medicine is “Nicardipine 10 mg/10 ml solution for injection” but in the rest of the leaflet it will be called as ‘Nicardipine solution for injection’.

What is in this leaflet

1. What Nicardipine solution for injection is and what it is used for
2. What you need to know before you are given Nicardipine solution for injection
3. How Nicardipine solution for injection will be given to you
4. Possible side effects
5. How to store Nicardipine solution for injection
6. Contents of the pack and other information

1. WHAT NICARDIPINE SOLUTION FOR INJECTION IS AND WHAT IT IS USED FOR

Pharmacotherapeutic group - ATC code: SELECTIVE CALCIUM INHIBITORS WITH VASCULAR EFFECTS - C08CA04 (cardiovascular system).
Nicardipine solution for injection contains the active substance nicardipine hydrochloride, which belongs to a group of medicines called calcium channel blockers.
Nicardipine solution for injection is used to treat very severe high blood pressure. It can also be used to control high blood pressure after an operation.
You must talk to a doctor if you do not feel better or if you feel worse.

2. WHAT YOU NEED TO KNOW BEFORE YOU ARE GIVEN NICARDIPINE SOLUTION FOR INJECTION

You must not be given Nicardipine solution for injection:

- if you are **allergic** to nicardipine or any of the other ingredients of this medicine (listed in section 6)
- if you have **chest pain**
- if your high blood pressure is because of **narrowing of a heart valve or other defects in the heart**
- if you have severe aortic stenosis (shrinking of the main artery from the heart)
 - if you have had a **heart attack** in the last eight days.

Warnings and precautions

Talk to your doctor or nurse before you are given Nicardipine solution for injection:

- If you have heart failure
- if you have angina
- if your kidneys are not working properly
- if your liver is not working properly, or you have had liver disease in the past
- if you have high pressure in the brain
- if you have suffered a recent stroke
- if you are taking beta-blockers
- if you are pregnant
 - if you are under 18 years of age

If you have these conditions, your doctor may need to monitor additional tests or change the dose. If any of the above apply to you, or you are not sure, tell your doctor before receiving **Nicardipine solution for injection**.

Other medicines and Nicardipine solution for injection

Tell your doctor if you are taking, have recently taken, or might take any other medicines. This includes medicines obtained without a prescription and herbal medicines. This is because Nicardipine solution for injection can affect the way some other medicines work. Also, some other medicines can affect the way Nicardipine solution for injection works.

In particular, tell your doctor if you are taking any of the following medicines:

- Dantrolene (used to treat long-term muscle stiffness)
- Beta-blockers (used to treat high blood pressure and heart conditions) such as propranolol, atenolol and metoprolol
- Medicines used to control seizures, such as carbamazepine, phenobarbitone, primidone, fosphenytoin and phenytoin
- Baclofen (used to treat muscle spasms)
- Medicines used to control the body's immune system, such as tacrolimus, sirolimus, everolimus, temsirolimus and ciclosporin
- Itraconazole, ketoconazole, voriconazole (used to treat certain types of fungal infection)
- Certain medicines used to treat certain viral diseases (boceprevir, ritonavir, telaprevir)
- Some antibiotics (clarithromycin, erythromycin, telithromycin)
- Rifampicin (used to treat tuberculosis and certain other types of infection)
- Alpha-blockers (used to treat high blood pressure, or prostate problems in men) such as alfuzosin, doxazosin, prazosin, silodosin, tamsulosin, terazosin and uradipil
- Any other medicine for high blood pressure
- Cimetidine (to treat indigestion or stomach ulcers)
- Digoxin (used for heart conditions)
- Amifostine (used to protect against the harmful effects of certain cancer treatments)
- Medicines to treat depression, anxiety or other mental health problems
- Strong painkilling medicines like morphine or codeine
- Medicines used to treat inflammation such as steroids and tetracosactide
- Magnesium injection (used to treat severe high blood pressure in pregnancy)
- Medicines used to treat chronic lymphocytic leukemia (delalalisib)
- Nitrated and related drugs
- Medicines causing orthostatic hypotension.

If you are having an operation, your anaesthetist will need to know which other medicines you are taking, as some of these can affect the way Nicardipine solution for injection works.

Nicardipine solution for injection with food and drink

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continued overleaf

The following information is intended for medical or healthcare professionals only:

Posology and method of administration:

Nicardipine solution for injection should be administered by continuous intravenous infusion only. It should only be administered by specialists in well controlled environments, such as hospitals and intensive care units, with continuous monitoring of blood pressure. The speed of administration must be accurately controlled by the use of an electronic syringe driver or a volumetric pump. Blood pressure and heart rate must be monitored at least every 5 minutes during the infusion, and then until vital signs are stable, but at least for 12 hours after the end of the administration of Nicardipine solution for injection.

The antihypertensive effect will depend on the administered dose. The dosage regimen to achieve the desired blood pressure can vary depending on the targeted blood pressure, the response of the patient, and the age or status of the patient.

Unless given by a central venous line, dilute to a concentration of 0.1 - 0.2 mg/ml before use.

Adults:

Initial dose: Treatment should start with the continuous administration of nicardipine at a rate of 3-5 mg/h for 15 minutes. Rates can be increased by increments of 0.5 or 1 mg every 15 minutes. The infusion rate should not exceed 15 mg/h.

Maintenance dose: When the target pressure is reached, the dose should be reduced progressively, usually to between 2 and 4 mg/h, to maintain the therapeutic efficacy.

Older patients:

Elderly patients may be more sensitive to nicardipine effects because of impaired renal and/or hepatic function. It is recommended to provide a continuous infusion of nicardipine starting at the dose of 1 to 5 mg/h, depending on the blood pressure and clinical situation. After 30 minutes, depending on the effect observed, the rate should be increased or decreased by increments of 0.5 mg/h. The rate should not exceed 15 mg/h.

Paediatric population:

Nicardipine solution for injection, safety and efficacy has not been established in low birth weight infants, newborns, nursing infants, infants and children.

Nicardipine should only be used for life-threatening hypertension in paediatric intensive care settings or post-operative contexts.

Initial dose: In case of emergency, a starting dose of 0.5 to 5 mcg/kg/min is recommended.

Maintenance dose: The maintenance dosage of 1 to 4 mcg/kg/min is recommended.

Nicardipine should be used with particular caution in children with renal impairment. In this case, only the lowest dose should be used.

Do not drink grapefruit juice or eat grapefruit whilst using this medication as it may increase blood levels of nicardipine.

Pregnancy and breast feeding

If you are pregnant or breast feeding, think you may be pregnant or are planning to have a baby, ask your doctor for advice before you are given this medicine.

Pregnancy

Nicardipine solution for injection should be used with caution in women in the third trimester of pregnancy as it could interfere with the spontaneous induction on labour.

Nicardipine solution for injection should not be used if you are having multiple children (twins or more) or if you have any issues with your heart except if no other suitable option is available.

Breast-feeding

Nicardipine solution for injection should not be used during breast-feeding.

Driving and using machines

Nicardipine solution for injection may affect the ability to drive or use machines. More particularly at the start or in case of modification of the treatment, as well as in combination with alcohol.

Nicardipine solution for injection contains sodium

This medicine contains less than 1 mmol sodium (23 mg) per ampoule that is to say essentially 'sodium-free'.

Nicardipine solution for injection contains sorbitol

Sorbitol is a source of fructose. If you (or your child) have hereditary fructose intolerance (HFI), a rare genetic disorder, you (or your child) must not receive this medicine. Patients with HFI cannot break down fructose, which may cause serious side effects.

You must tell your doctor before receiving this medicine if you (or your child) have HFI or if your child can no longer take sweet foods or drinks because they feel sick, vomit or get unpleasant effects such as bloating, stomach cramps or diarrhea.

3. HOW NICARDIPINE SOLUTION FOR INJECTION WILL BE GIVEN TO YOU

Always use this medicine exactly as your doctor has told you. Check with your doctor if you are not sure.

This medicine will be given to you in hospital.

Your doctor will decide on the amount of Nicardipine solution for injection you will be given. This will depend on how much and how fast they want to reduce your blood pressure.

The medicine will be injected slowly into a vein. Your blood pressure will be taken whilst you are receiving treatment and the dose adjusted to make sure your blood pressure fall to normal levels.

Nicardipine solution for injection will be given to you by a doctor, who will ensure that the correct dose is given for your condition. If you have any concerns tell your doctor or nurse.

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

If you are given more Nicardipine solution for injection than you should

Immediately consult your doctor or your pharmacist.

4. POSSIBLE SIDE EFFECTS

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

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

- Headache.

Other side effects include:

Common (may affect up to 1 in 10 people)

- Dizziness
- Increased heart rate, feeling your heartbeat (palpitations)
- Feeling sick or being sick

Not known (frequency cannot be estimated based on the available data)

- Reduction in blood platelets, which may increase the risk of bleeding or bruising
- Slow heart rhythm
- Heart problems leading to increased fluid in the lungs and shortness of breath
- Redness of the skin (erythema)
- Changes in blood tests of how your liver is working
- Cutaneous rash

- Swollen legs or ankles

- Low blood pressure, especially on standing up. This may cause dizziness, lightheadedness or fainting

- Cardiac rhythm disorders with decreased heart rate which may evolve in fainting

- Chest pain
- Abdominal pain
- Inflammation of the vein where the medicine has been given
- Allergic reactions
- Redness and flushing of the face.

Reporting of side effects

If you get any side effects, talk to your doctor 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 website: 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 NICARDIPINE SOLUTION FOR INJECTION

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, carton after EXP.

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

Before opening

Do not store above 25°C.

Store in the original container in order to protect from light.

After opening

The physicochemical stability of the undiluted solution or diluted in a solution of 5% dextrose in water in a polypropylene syringe has been demonstrated for 24 hours at temperatures of +25°C, away from light.

Nonetheless, from a microbiological standpoint, the product should be used immediately.

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 Nicardipine solution for injection contains

The active substance is nicardipine. Each **Nicardipine solution for injection** ampoule contains nicardipine hydrochloride 10 mg/10 ml.

The other ingredients are sorbitol, citric acid monohydrate, sodium citrate, hydrochloric acid, sodium hydroxide and water for injections.

What Nicardipine solution for injection looks like and contents of the pack

Nicardipine solution for injection is a clear, pale yellow colored solution. It is available in brown glass ampoules containing 10ml of the solution for injection.

Each pack contains 5, 10 or 50 ampoules. Not all pack sizes may be marketed.

Marketing Authorisation Holder

Laboratoire AGUETTANT

1 Rue Alexander Fleming, 69007 LYON, France.

Manufacturer

Laboratoire AGUETTANT

1 Rue Alexander Fleming, 69007 LYON, France.

This leaflet was last revised in 07/2021.

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Pregnancy:

It is recommended to provide a continuous infusion of nicardipine starting at 1 to 5 mg/h, depending on the blood pressure and clinical situation. After 30 minutes, depending on the effect observed, this rate can be increased or decreased by increments of 0.5 mg/h.

Doses higher than 4mg/h are generally not exceeded in the treatment of pre-eclampsia, however the rate should not exceed 15 mg/h. The use of nicardipine for severe pre-eclampsia during the third trimester of pregnancy could potentially produce an undesirable tocolytic effect which could potentially interfere with the spontaneous induction of labour.

Acute pulmonary oedema has been observed when nicardipine has been used as tocolytic during pregnancy, especially in cases of multiple pregnancy (twins or more), with the intravenous route and/or concomitant use of beta-2 agonists. Nicardipine should not be used in multiple pregnancies or in pregnant women with compromised cardio-vascular condition, except if there is no other acceptable alternative.

Hepatic Impairment:

Nicardipine should be used with particular caution in these patients. It is recommended to use the same dose regimens as for elderly patients in patients with impaired liver function or reduced hepatic blood flow.

Renal Impairment:

Nicardipine should be used with particular caution in these patients. It is recommended to use the same dose regimens as for elderly patients in patients with renal impairment.

Incompatibilities:

Nicardipine solution for injection should not be mixed with other medicinal products except those mentioned under posology and method of administration section.

A risk of precipitation exists with products presenting a pH in solution greater than 6. A risk of adsorption of nicardipine exists on plastic materials in devices for infusion in the presence of saline solutions.

Shelf life:

Before opening: 2 years.

After opening: The physicochemical stability of the undiluted solution or diluted in a solution of 5% dextrose in water in a polypropylene syringe has been demonstrated for 24 hours at temperatures of +25°C, away from light. Nonetheless, from a microbiological standpoint, the product should be used immediately.