Nicardipine solution for injection contains the active substance Nicardipine hydrochloride, which belongs to a group of medicines called calcium channel blockers. The infusion rate should not exceed 15 mg/h. Adults: Unless given by a central venous line, dilute to a concentration of 0.1 - 0.2 mg/ml before use. Of the patient, and the age or status of the patient. 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. The following information is intended for medical or healthcare professionals only:

Posology and method of administration:

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. Elderly: 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 posology should be used.
Nicardipine solution for injection

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

Pregnancy and breast feeding

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.

Driving and using machines

Nicardipine solution for injection does not affect your ability to drive and use machines.

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

Nicardipine 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 TO TAKE NICARDIPINE SOLUTION FOR INJECTION

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 falls 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.

4. POSSIBLE SIDE EFFECTS

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

Headache is the most common side effect, which may affect more than 1 in 10 people.

Other side effects include:

- Common (may affect up to 1 in 10 people)
  - Dizziness
  - Increased heart rate, feeling your heart beat (palpitations)
  - Feeling sick or being sick
- Uncommon (may affect up to 1 in 100 people)
  - Swollen legs or ankles
  - Low blood pressure, especially on standing up. This may cause dizziness, lightheadedness or fainting
- Rare (may affect less than 1 in 100 people)
  - Slow heart rhythm
- Very rare (may affect less than 1 in 10,000 people)
  - Heart problems leading to increased fluid in the lungs and shortness of breath
  - Changes in blood tests of how your liver is working
  - Allergic reactions.

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: 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.

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.

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 10mg/10ml.

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

Mercury Pharmaceuticals Limited, Capital House, 85 King William Street, London EC4N 7BL, UK

Manufacturer

Laboratoire Aguettant, 1 Rue Alexander Fleming, 69007 Lyon, France.

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