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European Medicines Agency gives recommendations on the use of intravenous nicardipine

On 24 October 2013, the European Medicines Agency completed a benefit-risk review of intravenous (given into a vein) nicardipine medicines. The Agency's Committee on Medicinal Products for Human Use (CHMP) concluded that these medicines should only be used to treat acute (sudden) life-threatening high blood pressure and to control high blood pressure after an operation. Use of intravenous nicardipine medicines in other indications is no longer recommended.

The CHMP also recommended that these medicines should only be given by continuous infusion (drip) into a vein by a specialist in a hospital or intensive care unit.

Detailed information on the recommended uses of intravenous nicardipine, including instructions on how to use these medicines, can be found below.

The review of intravenous nicardipine was triggered by the UK medicines regulatory agency (MHRA), following submission in the UK of an application for a generic intravenous nicardipine medicine. The MHRA was concerned that the clinical data submitted were inadequate to determine the benefits and risks of the generic medicine in the proposed indications. It also noted that medicines containing nicardipine given intravenously had been authorised in other EU countries but that the authorised uses differed between countries. The MHRA therefore decided to request an EU-wide review of these medicines.

Having assessed the available evidence on the safety and effectiveness of intravenous nicardipine from published studies and post-marketing data, the CHMP concluded that an intravenous formulation of nicardipine is a useful treatment for high blood pressure in specific settings and with appropriate specialist intervention and monitoring.

The CHMP opinion was sent to the European Commission, which endorsed it and adopted a final legally binding decision valid throughout the EU on 20 December 2013.

Information to patients

- An EU-wide review of medicines containing nicardipine given into a vein has been carried out and recommendations have been given to ensure the safe and effective use of these medicines.

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- Medicines containing nicardipine given into a vein should be used to treat very severe high blood pressure, or to control high blood pressure after an operation.
- These medicines will be given to you in hospital as a drip into a vein, and your blood pressure will be regularly monitored.
- If you have any questions or concerns, speak to your doctor, pharmacist or nurse.

Information to healthcare professionals

The EU-wide review of intravenous nicardipine has resulted in updated prescribing information for these medicines.

The recommended therapeutic indications of intravenous nicardipine are now:

- treatment of acute life-threatening hypertension, particularly in the event of:
  - malignant arterial hypertension/hypertensive encephalopathy;
  - aortic dissection, when short acting beta-blocker therapy is not suitable, or in combination with a beta-blocker when beta-blockade alone is not effective;
  - severe pre-eclampsia, when other intravenous antihypertensive agents are not recommended or are contra-indicated;
- treatment of post-operative hypertension.

Nicardipine was also used in some EU countries for controlled hypotension during anaesthesia, for controlling hypertension during surgery and for treating acute severe hypertension with left ventricular decompensation and pulmonary oedema. These uses are no longer recommended because the available data are insufficient to support use in these conditions.

Regarding the posology, nicardipine should be administered by continuous intravenous infusion. It should only be administered by specialists in well controlled environments, with continuous monitoring of blood pressure.

In adults, treatment should start with a continuous administration of nicardipine at a rate of 3-5 mg/h. The rate can then be increased but should not exceed 15 mg/h. When the target blood pressure is reached, the dose should be reduced progressively. Nicardipine should be used with caution and at lower doses in specific patient populations, including patients with liver and kidney problems and children.

More about the medicine

Nicardipine is an ‘antihypertensive’ medicine that reduces blood pressure by allowing the blood vessels to relax. It works as a ‘calcium-channel blocker’: this means that it blocks special channels on the surface of cells called calcium channels, through which calcium ions normally enter the cells. When calcium ions enter the cells in the muscles of blood vessel walls, this causes contraction. By reducing the flow of calcium into the cells, nicardipine prevents the cells from contracting and this helps the blood vessels to relax.

Medicines containing nicardipine given into a vein are authorised in the following EU Member States: Belgium, France, Luxemburg, the Netherlands and Spain.

More about the procedure

The review of intravenous nicardipine was initiated in July 2012 at the request of the United Kingdom, under Article 31 of Directive 2001/83/EC. The UK medicines agency asked the CHMP to carry out an assessment of the benefit-risk balance of intravenous nicardipine and to issue an opinion on whether the marketing authorisations of these medicines should be maintained, varied, suspended or withdrawn across the European Union.

The CHMP recommendation was sent to the European Commission, which issued a final decision on 20 December 2013.

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