Intravenous nicardipine: instructions for use <Date>

Dear Healthcare Professional,

Amdipharm Mercury Company Limited, in agreement with the Medicines and Healthcare Products Regulatory Agency, would like to inform you of the following:

Summary

- Intravenous nicardipine should only be used to treat acute life-threatening hypertension and post-operative hypertension.
- Nicardipine should be administered by a specialist and in a well-controlled environment (e.g. hospital or intensive care unit).
- In adults, start continuous infusion 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, gradually reduce the dose.
- Blood pressure should be monitored continuously during infusion and for at least 12 hours after the end of the infusion.

Further information

Nicardipine is an antihypertensive calcium-channel blocker.

A European regulatory review assessed the available evidence on the safety and effectiveness of intravenous nicardipine from published studies and clinical practice data. The review 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.

Indications

Intravenous nicardipine is indicated for the treatment of acute life-threatening hypertension, particularly in the event of:

- malignant arterial hypertension or 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

Nicardipine is also indicated for the treatment of post-operative hypertension.
There are insufficient data to support intravenous nicardipine use for any other indications (eg, acute severe hypertension with left ventricular decompensation and pulmonary oedema). Therefore intravenous nicardipine use for indications other than those stated above is not recommended.

Method of administration

Intravenous nicardipine should only be administered by a specialist and in a well-controlled environment (e.g. hospital or intensive care unit).

Administer nicardipine by continuous infusion. Control infusion speed with an electronic syringe driver or a volumetric pump. In adults, start continuous infusion 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, gradually reduce the dose, usually to between 2-4 mg/h to maintain efficacy. .

Monitor blood pressure and heart rate at least every 5 minutes during the infusion and then until vital signs are stable, but for at least 12 hours after the end of infusion.

Use nicardipine with caution and at lower doses in specific patient populations (e.g. children, patients with liver or kidney problems).

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 and health status of the patient. For more information please see the summary of product characteristics (Annex 1) and patient information leaflet (Annex 2).

Please share this information with relevant colleagues and health care personnel.

Call for reporting of side effects

Please report suspected side effects of any medicine or vaccine to the MHRA through the Yellow Card Scheme online at www.mhra.gov.uk/yellowcard. Alternatively, prepaid Yellow Cards for reporting are available:

- upon request by mail: "FREEPOST YELLOW CARD"
- at the back of the British National Formulary (BNF)
- by telephoning the Commission on Human Medicines (CHM) free phone line: 0800-731-6789
- Or by electronic download through the Yellow Card section of the MHRA website

When reporting please provide as much information as possible, including medical history, any concomitant medication, timing of side effect onset, and treatment dates.

Company contact point

Should you have any questions or require additional information please contact Amdipharm Mercury Medical Information department on:
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Yours sincerely,

Dr. Bharat Karbal
Medical and Regulatory Affairs Director

Annexes
1. Summary of Product Characteristics
2. Patient Information Leaflet