

## COMPANY CONTACT POINT

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

**Email:** [medicalinformation@amcolimited.com](mailto:medicalinformation@amcolimited.com).

**Tel:** + 44 (0) 208 588 9100

**Fax:** + 44 (0) 208 588 9200

## REFERENCES

1. European Medicines Agency gives recommendations on the use of intravenous Nicardipine.  
[http://www.ema.europa.eu/ema/index.jsp?curl=pages/news\\_and\\_events/news/2013/10/news\\_detail\\_001928.jsp&mid=WC0b01ac058004d5c1](http://www.ema.europa.eu/ema/index.jsp?curl=pages/news_and_events/news/2013/10/news_detail_001928.jsp&mid=WC0b01ac058004d5c1)
2. Medicines Complete. Martindale: The complete drug reference [http://www.medicinescomplete.com/mc/martindale/current/13008-c.htm?q=Nicardipine&t=search&ss=text&p=1#\\_hit](http://www.medicinescomplete.com/mc/martindale/current/13008-c.htm?q=Nicardipine&t=search&ss=text&p=1#_hit) on 06-Mar-2014



# Important information for Prescribers and other Health Care Professionals

## Nicardipine 10 mg/10ml solution for injection



Amdipharm Mercury Company Ltd,  
Capital House, 85 King William Street,  
London EC4N 7BL, UK  
Tel +44 (0) 208 588 9100  
Fax +44 (0) 208 588 9200  
Email: [medicalinformation@amcolimited.com](mailto:medicalinformation@amcolimited.com)

Amdipharm Mercury Company Ltd,  
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London EC4N 7BL, UK  
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Fax +44 (0) 208 588 9200  
Email: [medicalinformation@amcolimited.com](mailto:medicalinformation@amcolimited.com)

## HCP BROCHURE - NICARDIPINE 10 MG/10ML SOLUTION FOR INJECTION

This item is to provide you with important information about the indications, mode of administrations and safety precautions to be followed while using IV Nicardipine.

### ABOUT NICARDIPINE

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.

### INDICATIONS

Intravenous nicardipine is used to treat high blood pressure in specific settings and with **appropriate specialist intervention** and **monitoring**.

The therapeutic indications of intravenous nicardipine are:

1. The 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.
2. The treatment of post-operative hypertension.

### CONTRAINDICATIONS

- Known hypersensitivity to Nicardipine or to any of the excipients listed in the Summary of Product Characteristics (SmPC).
- Severe aortic stenosis
- Compensatory hypertension, i.e. in case of an arteriovenous shunt or aortic co-arcation.
- Unstable angina
- Within 8 days after myocardial infarction

## METHOD OF ADMINISTRATION

Nicardipine should be administered only by continuous **intravenous infusion by specialists** in well controlled environments, such as **hospitals and intensive care units, with continuous monitoring of blood pressure**.

**Points to remember during the administration of IV Nicardipine:**

- 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.
- **Infusion site reactions** can occur, particularly with prolonged duration of administration and in peripheral veins. It is advised to change the infusion site in case of any suspicion of infusion site irritation. The use of a central venous line or of a greater dilution of the solution could reduce the risk of occurrence of infusion site reaction.

### DOSING

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. For more information on dosing please see the summary of product characteristics.

### 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.