**Presentation:** Solution for injection containing 10mg/10ml nicardipine hydrochloride.

**Indication:** Treatment of acute life-threatening hypertension, particularly in the event of malignant arterial hypertension/hypertensive encephalopathy, aortic dissection (when a 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 anti hypertensive agents are not recommended or contra-indicated) and treatment of post-operative hypertension.

**Dosage and administration:**

**Route of administration:** Continuous intravenous infusion only.

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. **Adults:** Initial dose: Treatment should start at a rate of 3-5 mg/h for 15 minutes. Rates can be increased by increments of 0.5-1 mg every 15 minutes to a maximum of 15 mg/h. Maintenance dose: The dose should be reduced progressively, usually to between 2-4 mg/h, to maintain the therapeutic efficacy. **Elderly:** Initial dose of 1-5 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. **Children:** Initial dose: In case of emergency, a starting dose of 0.5-5 mcg/kg/min is recommended. Maintenance dose: Doses of 1 to 4 mcg/kg/min are recommended.

**Contraindications:** Known hypersensitivity to nicardipine or to any of the excipients, severe aortic stenosis, compensatory hypertension, unstable angina, within 8 days following a myocardial infarction, and in rare hereditary problems of fructose intolerance.

**Precautions and warnings:** Use with caution when using in combination with beta-blocker. Infusion site reactions can occur, particularly with prolonged duration of administration and in peripheral veins. Rapid pharmacologic reductions in blood pressure may produce systemic hypotension and reflex tachycardia. Caution in patients with congestive heart failure, pulmonary oedema, ischaemic cardiovascular disease, impaired hepatic or renal function, portal hypertension, pre-existing intracranial function and stroke.

**Interactions:** Beta-blockers, dantrolene, magnesium, CYP3A4 inducers and inhibitors, cyclosporine, tacrolimus, digoxin, baclofen, alpha-blockers, tricyclic antidepressants, neuroleptics, opioids, amifostine, intravenous corticosteroids and tetracosactide, inhalational anaesthetics.

**Pregnancy:** The use of nicardipine during the first two trimesters in a limited number of pregnancies has not revealed any malformative or particular foetotoxic effects to date. 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. 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.

**Lactation:** Nicardipine should not be used during breast-feeding.

**Undesirable effects:** **Very common:** headache. **Common:** dizziness, lower limb oedema, palpitations, hypotension, tachycardia, orthostatic hypotension, nausea, vomiting, flushing. *(Please refer to the Summary of Product Characteristics for detailed information)*

**Overdose:** Symptoms include marked hypotension, bradycardia, palpitations, flushing, drowsiness, collapse, peripheral oedema, confusion, slurred speech and hyperglycaemia. Management includes general supportive measures such as monitoring of cardiac and respiratory function.

**Legal category:** POM

**Basic NHS cost:** £50.00 for 5 x 10ml ampoules

**Marketing Authorisation Number:** PL 12762/0450

**Marketing Authorisation Holder:** Amdipharm Mercury Company Limited (AMCo), 1st Floor, Capital House, 85 King William Street, London, EC4N 7BL

**Date of preparation:** April 2015

Adverse events should be reported to the local regulatory authority.

Reporting forms and information can be found at [www.mhra.gov.uk/yellowcard](http://www.mhra.gov.uk/yellowcard).

Adverse events should also be reported to Amdipharm Mercury Medical Information via telephone on 08700 70 30 33 or via e-mail at medicalinformation@amcolimited.com.