

**Annex I**

**Scientific conclusions and grounds for the variation to the terms of the Marketing Authorisation(s)**

## **Scientific conclusions**

Taking into account the PRAC Assessment Report on the PSUR(s) for nicardipine, the scientific conclusions are as follows:

### **Hypoxia**

In view of available data on hypoxia from clinical studies, the literature, spontaneous reports including in most cases a close temporal relationship, a positive de-challenge and/or re-challenge and in view of a plausible mechanism of action, the Lead Member State considers a causal relationship between nicardipine and hypoxia is at least a reasonable possibility. The Lead Member State concluded that the product information of products containing nicardipine should be amended accordingly.

Having reviewed the PRAC recommendation, the CMDh agrees with the PRAC overall conclusions and grounds for recommendation.

### **Grounds for the variation to the terms of the marketing authorisation(s)**

On the basis of the scientific conclusions for nicardipine the CMDh is of the opinion that the benefit-risk balance of the medicinal product(s) containing nicardipine is unchanged subject to the proposed changes to the product information.

The CMDh recommends that the terms of the marketing authorisation(s) should be varied.

## **Annex II**

**Amendments to the product information of the nationally authorised medicinal product(s)**

**Amendments to be included in the relevant sections of the Product Information** (new text **underlined and in bold**, deleted text ~~strike-through~~)

## Summary of Product Characteristics

For all nicardipine formulations

- Section 4.4- Special warnings and precautions for use

A warning should be added as follows:

### **Hypoxia**

**Cases of hypoxia have been reported after intravenous administration of nicardipine, particularly in patients with pre-existing pulmonary disorders or other conditions that may compromise respiratory function. Careful monitoring of oxygenation is recommended in these patients.**

For nicardipine intravenous formulations only

Add a cross reference in section 4.4 **(see section 4.8)**.

- Section 4.8

The following adverse reaction should be added under the SOC "Respiratory, thoracic and mediastinal disorders" with a frequency "unknown":

### **Hypoxia**

## Package Leaflet

For all nicardipine formulations

Section 2

**This medicine may cause low oxygen levels or breathing difficulties when given by injection into a vein, especially in patients with lung problems or other conditions affecting breathing. Your doctor will check your oxygen levels during treatment.**

For nicardipine intravenous formulations only

Section 4 – Possible side effects

Respiratory, thoracic and mediastinal disorders

**Low oxygen levels in the blood (hypoxia) – frequency not known**

**Annex III**

**Timetable for the implementation of this position**

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Adoption of CMDh position:	January 2026 CMDh meeting
Transmission to National Competent Authorities of the translations of the annexes to the position:	15 March 2026
Implementation of the position by the Member States (submission of the variation by the Marketing Authorisation Holder):	14 May 2026