

Public Summary SwissPAR dated 11 June 2021

Nicardipin Labatec[®] (active substance: nicardipine hydrochloride)

First authorisation in Switzerland: 22 March 2021

Medicinal product (solution for injection) for the treatment of acute, life-threatening high blood pressure

Information on authorisation

The medicinal product Nicardipin Labatec contains the active substance nicardipine hydrochloride and is a solution for injection into the veins.

Nicardipin Labatec has been authorised in Switzerland for the treatment of acute, life-threatening high blood pressure (hypertension).

Nicardipin Labatec is also used for the treatment of high blood pressure as a consequence of surgery.

Nicardipin Labatec was authorised under Art. 14 para. 1 let. a^{bis} of the Therapeutic Products Act (TPA). The TPA enables certain categories of medicines to be authorised according to a simplified procedure, provided this is compatible with the quality, safety and efficacy requirements and there is no conflict with Swiss interests or international obligations.

At the time the application was submitted, Nicardipin Labatec, containing the active substance nicardipine hydrochloride, had demonstrably been used in a medicinal

product that had been authorised for at least 10 years in at least one EU or EFTA country, and that is comparable in terms of indications, dosage and method of administration. The preconditions for simplified authorisation were therefore met.

Consequently, Swissmedic is not conducting its own comprehensive scientific review, and the preconditions for a SwissPAR (Swiss Public Assessment Report) and a resulting Public Summary SwissPAR do not apply. Swissmedic refers to the authorisation of the foreign comparator medicinal product: <https://www.ema.europa.eu>

The authorisation of Nicardipin Labatec is based on the medicinal product Nicardipin Aguetant 10 mg/ml, which contains the same active substance and has been authorised in France for more than 10 years.

Further information on simplified authorisation according to Art. 14 TPA can be found in the Federal Act on Medicinal Products and Medical Devices (Therapeutic Products Act, TPA).

Further information on the medicinal product

Information for healthcare professionals (de):

[Fachinformation Nicardipin Labatec®](#)

Healthcare professionals (doctors, pharmacists and others) can answer any further questions about this medicine.

The date of revision of this text corresponds to that of the SwissPAR. New information concerning the authorised medicinal product in question will not be incorporated into the Public Summary SwissPAR.

Swissmedic monitors medicinal products authorised in Switzerland. Swissmedic initiates the necessary action in the event of newly discovered adverse drug reactions or other safety-relevant signals. New findings that could impair the quality, efficacy or safety of this medicinal product are recorded and published by Swissmedic. If necessary, the medicinal product information is adapted.