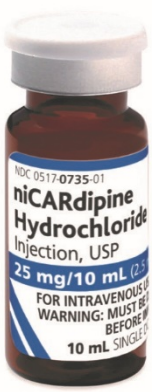
American Regent Introduces niCARdipine Hydrochloride Injection, USP; Therapeutically Equivalent to Cardene®[1, 2]



Nicardipine Hydrochloride Injection is supplied in a 10 mL amber glass vial in a carton of 10 vials. The strength is 25 mg/10 mL (2.5 mg/mL).

Shirley, NY – May 7, 2020: American Regent announced the introduction of the only FDA approved USP standard Nicardipine Hydrochloride Injection. Nicardipine Hydrochloride is a calcium channel blocker indicated for the short-term treatment of hypertension when oral therapy is not feasible.

"American Regent is pleased to be bringing back this shortage-prone product in a USP formulation, and to offer health care providers another option for the treatment of hypertension," stated Harsher Singh, Vice President, Chief Commercial and Strategic Officer at American Regent, Inc.

This product is available for immediate shipment. Customers can order Nicardipine Hydrochloride Injection, USP through their wholesaler/distributor, or by contacting our Customer Support Group at 1-800-645-1706.

Nicardipine Hydrochloride Injection, USP is supplied as follows:

Pack NDC#	Strength	Supplied As	Shelf Pack
0517-0735-10	25 mg/10 mL (2.5 mg/mL)	10 mL Single Dose Vial	10

See the following Important Safety Information in addition to the product's Full Prescribing Information.

For additional information, please visit www.americanregent.com.

References

1. Cardene® is a registered trademark of Chiesi USA, Inc.

2. Data on file. FDA Approval Letter ANDA 090534. Shirley, NY American Regent, Inc.

265 Broadhollow Road \\ 4th Floor \\ Melville, NY 11747
T 631.924.4000 \\ **F** 631.924.1731

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niCARdipine Hydrochloride Injection, USP

For Intravenous Use

VIALS MUST BE DILUTED BEFORE INFUSION

INDICATIONS AND USAGE: Nicardipine hydrochloride injection is indicated for the short-term treatment of hypertension when oral therapy is not feasible or not desirable. For prolonged control of blood pressure, transfer patients to oral medication as soon as their clinical condition permits.

IMPORTANT SAFETY INFORMATION

Contraindications: Do not use in patients with advanced aortic stenosis.

WARNINGS AND PRECAUTIONS

Closely monitor response in patients not limited to those with angina, heart failure, impaired hepatic function or renal impairment and avoid too rapid or excessive blood pressure drop during treatment.

Local Irritation

To reduce the possibility of venous thrombosis, phlebitis, local irritation, swelling, extravasation, and the occurrence of vascular impairment, administer drug through large peripheral veins or central veins. To minimize the risk of peripheral venous irritation, change the site of the drug infusion every 12 hours.

ADVERSE REACTIONS

Most common adverse reactions are headache (15%), hypotension (6%), tachycardia (4%) and nausea/vomiting (5%).

Post-Marketing

Because adverse reactions are reported voluntarily from a population of uncertain size, it is not always possible to estimate reliably their frequency or to establish a causal relationship to drug exposure.
The following adverse reaction has been identified during post-approval use of nicardipine hydrochloride injection: decreased oxygen saturation (possible pulmonary shunting).

USE IN SPECIFIC POPULATIONS

Pregnancy: Pregnancy Category C. Based on animal data may cause fetal harm. Nicardipine hydrochloride injection should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus.

Nursing mothers: Minimally excreted into human milk. Consider the possibility of infant exposure.

Pediatric Use: Safety and efficacy in patients under the age of 18 have not been established.

OVERDOSAGE

For treatment of overdosage, implement standard measures including monitoring of cardiac and respiratory functions.

For additional safety information, please see Full Prescribing Information.

You are encouraged to report Adverse Drug Events to American Regent, Inc. at 1-800-734-9236, or to the FDA by visiting www.fda.gov/medwatch or by calling 1-800-FDA-1088.

You are encouraged to report Adverse Drug Events (ADEs) to American Regent:
Email: pv@americanregent.com; **Fax:** 1-610-650-0170;
Phone: 1-800-734-9236

ADEs may also be reported to the FDA:
1-800-FDA-1088 or to www.fda.gov/medwatch

Drug Information:
1-888-354-4855
(9:00 am – 5:00 pm Eastern Time, Monday – Friday)

For urgent drug information outside of normal business hours,
assistance is available at:
1-877-845-6371

About American Regent
American Regent, Inc., a Daiichi Sankyo Group company, is a top-10 injectable manufacturer. For over 50 years, American Regent has been developing, manufacturing and supplying quality generic and branded injectables for healthcare providers. For nearly 20 years, we have been a leader in IV iron therapy.

American Regent is committed to US-based manufacturing. In 2018, more than 99% of units supplied were manufactured in our US-based facilities, making us uniquely positioned to quickly mobilize and respond to shortages or changes in market needs.

Speed counts. Flexibility matters. Reliability and quality are paramount. Because patients should never have to wait for the medications they need.

For more information, please visit www.americanregent.com.

About Daiichi Sankyo Group
Daiichi Sankyo Group is dedicated to the creation and supply of innovative pharmaceutical therapies to improve standards of care and address diversified, unmet medical needs of people globally by leveraging our world-class science and technology. With more than 100 years of scientific expertise and a presence in more than 20 countries, Daiichi Sankyo and its 15,000 employees around the world draw upon a rich legacy of innovation and a robust pipeline of promising new medicines to help people. In addition to a strong portfolio of medicines for cardiovascular diseases, under the Group's 2025 Vision to become a "Global Pharma Innovator with Competitive Advantage in Oncology," Daiichi Sankyo is primarily focused on providing novel therapies in oncology, as well as other research areas centered around rare diseases and immune disorders.

For more information, please visit: www.daiichisankyo.com.

Daiichi Sankyo, Inc., headquartered in Basking Ridge, New Jersey, is a member of the Daiichi Sankyo Group.
For more information on Daiichi Sankyo, Inc., please visit: www.dsi.com.