



For Immediate Release

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## American Regent Announces the Availability of AP-rated 10% Calcium Chloride Injection, USP<sup>1,2</sup>

Shirley, NY (November XX, 2017) – American Regent today announced the launch of 10% Calcium Chloride Injection, USP. **10% Calcium Chloride Injection, USP is available for immediate shipment. Customers can order 10% Calcium Chloride Injection, USP through their wholesaler/distributor or by contacting our Customer Support Group at 1-800-645-1706.**

10% calcium chloride injection is indicated for the treatment of hypocalcemia in those conditions requiring a prompt increase in plasma calcium levels. 10% Calcium Chloride Injection, USP is supplied as follows:

NDC#	Strength	Supplied As	Shelf Pack
0517-6710-10	100 mg/mL	10 mL Single Dose Vial*	10

\* The vial closure is not made with natural rubber latex.

See the following Important Safety Information in addition to the [Full Prescribing Information](#).

**10% Calcium Chloride Injection, USP****For Intravenous Use Only.****A HYPERTONIC SOLUTION IN A 10 ML SINGLE DOSE VIAL FOR PROMPT INTRAVENOUS INJECTION.**

**CAUTION:** This solution should not be injected intramuscularly or subcutaneously. Administer only by slow injection.

**INDICATIONS AND USAGE**

10% calcium chloride injection is indicated for the treatment of hypocalcemia in those conditions requiring a prompt increase in plasma calcium levels.

**IMPORTANT SAFETY INFORMATION****CONTRAINDICATIONS**

Calcium chloride is contraindicated for cardiac resuscitation in the presence of ventricular fibrillation or in patients with the risk of existing digitalis toxicity.

Calcium chloride is not recommended in the treatment of asystole and electromechanical dissociation.

**WARNINGS**

10% calcium chloride injection is irritating to veins and must not be injected into tissues, since severe necrosis and sloughing may occur. Great care should be taken to avoid extravasation or accidental injection into perivascular tissues.

This product contains aluminum that may be toxic. Premature neonates are particularly at risk because their kidneys are immature, and they require large amounts of calcium and phosphate solutions, which contain aluminum.

**PRECAUTIONS**

Because of its additive effect, calcium should be administered very cautiously to a patient who is digitalized or who is taking effective doses of digitalis or digitalis-like preparations.

It is particularly important to prevent a high concentration of calcium from reaching the heart because of the danger of cardiac syncope.

**Pregnancy:** Calcium chloride should be given to a pregnant woman or a woman of childbearing potential only if clearly needed.

**Pediatric Use:** Safety and effectiveness are based on similar clinical conditions in children and adults.

**Geriatric Use:** In general, dosing for a geriatric patient should be cautious.

#### **ADVERSE REACTIONS**

Rapid injection may cause the patient to complain of tingling sensations, a calcium taste, a sense of oppression or "heat wave". Injections of calcium chloride are accompanied by peripheral vasodilatation as well as a local "burning" sensation and there may be a moderate fall in blood pressure.

#### **OVERDOSAGE**

Too rapid injection may produce lowering of blood pressure and cardiac syncope.

For additional safety information, please see Full Prescribing Information.

**You are encouraged to report Adverse Drug Events to American Regent Inc. at 1-888-734-9236 or to the FDA by visiting [www.fda.gov/medwatch](http://www.fda.gov/medwatch) or calling 1-800-FDA-1088.**

#### **About American Regent**

Celebrating 50 years as a manufacturer and marketer of branded and generic specialty injectables, American Regent, a Daiichi Sankyo Group Company, is proud of its reputation as a consistent and reliable source of high quality pharmaceuticals. Through our multiple US based manufacturing facilities, American Regent is able to maintain strict control of the manufacturing process to help provide a steady supply of products that our customers can depend on.

For more information, please visit [www.americanregent.com](http://www.americanregent.com).

## About Daiichi Sankyo

Daiichi Sankyo Group is dedicated to the creation and supply of innovative pharmaceutical products to address diversified, unmet medical needs of patients in both mature and emerging markets. With over 100 years of scientific expertise and a presence in more than 20 countries, Daiichi Sankyo and its 16,000 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 hypertension and thrombotic disorders, under the Group's 2025 Vision to become a "Global Pharma Innovator with a Competitive Advantage in Oncology," Daiichi Sankyo research and development is primarily focused on bringing forth novel therapies in oncology, including immuno-oncology, with additional focus on new horizon areas, such as pain management, neurodegenerative diseases, heart and kidney diseases, and other rare diseases. For more information, please visit: [www.daiichisankyo.com](http://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](http://www.dsi.com).

**References:** 1. Approved Drug Products with Therapeutic Equivalence Evaluations. [https://www.accessdata.fda.gov/scripts/cder/ob/results\\_product.cfm?Appl\\_Type=A&Appl\\_No=209088](https://www.accessdata.fda.gov/scripts/cder/ob/results_product.cfm?Appl_Type=A&Appl_No=209088) Updated January 25, 2017. Accessed September 28, 2017. 2. Calcium Chloride [Package Insert]. American Regent, Inc.; 2017: Shirley, NY.