

American Regent introduces FDA-approved Vasopressin Injection, USP



Vasopressin Injection is supplied as a 1 mL single-dose vial with a strength of 20 Units per mL.

Melville, NY – February 3, 2022: American Regent announces the introduction and availability of FDA-approved Vasopressin Injection, USP. Vasopressin is indicated to increase blood pressure in adults with vasodilatory shock who remain hypotensive despite fluids and catecholamines.

"We are pleased to provide this critical medication for patients who need it. The approval of Vasopressin represents our commitment to providing the market with access to competitively priced treatment options," stated Joann Gioia, Vice President, Chief Commercial Officer at American Regent, Inc.

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

Vasopressin Injection is supplied as follows:

Pack NDC#	Strength	Supplied as	Shelf pack
0517-1020-25	20 units per mL	1 mL Single-dose vial	25

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

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

PP-VI-US-0005 1/2022

Vasopressin Injection, USP

For intravenous use. Dilute prior to administration.

INDICATIONS AND USAGE

Vasopressin injection is indicated to increase blood pressure in adults with vasodilatory shock who remain hypotensive despite fluids and catecholamines.

IMPORTANT SAFFTY INFORMATION

CONTRAINDICATIONS

Vasopressin injection is contraindicated in patients with known allergy or hypersensitivity to 8-L-arginine vasopressin or chlorobutanol.

WARNINGS AND PRECAUTIONS

Can worsen cardiac function.

Patients may experience reversible diabetes insipidus.

ADVERSE REACTIONS

The most common adverse reactions included decreased cardiac output, bradycardia, tachyarrhythmias, hyponatremia, and ischemia (coronary, mesenteric, skin, digital).

The following additional adverse reactions were identified:

Bleeding/lymphatic system disorders: Hemorrhagic shock, decreased platelets, intractable bleeding

Cardiac disorders: Right heart failure, atrial fibrillation, bradycardia, myocardial ischemia

Hepatobiliary: Increased bilirubin levels

Renal/urinary disorders: Acute renal insufficiency

Vascular disorders: Distal limb ischemia

DRUG INTERACTIONS

Hemodynamic monitoring is recommended; adjust the dose of vasopressin as needed.

USE IN SPECIFIC POPULATIONS

Pregnancy: May induce tonic uterine contractions.

Pediatric Use: Safety and effectiveness have not been established.

Geriatric Use: Dose selection for an elderly patient should be cautious.

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:

T 1.800.734.9236 E pv@americanregent.com F 1.610.650.0170

ADEs may also be reported to the FDA:

1.800.FDA.1088 or to www.fda.gov/medwatch

Medical information:

T 1.888.354.4855 (9:00 am – 5:00 pm Eastern Time, Monday – Friday) www.americanregent.com/medical-affairs

For medical information outside of normal business hours, that cannot wait until the next business day, please call 1.877.845.6371

About American Regent

American Regent, Inc., a Daiichi Sankyo Group company, is a leading 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. To that end, over the last several years, we have made significant investments in expanding and modernizing our manufacturing facilities in Ohio and New York. This expansion will nearly double our capacity and allow us to better serve our customers now and in the future.

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 is dedicated to creating new modalities and innovative medicines by leveraging our world-class science and technology for our purpose "to contribute to the enrichment of quality of life around the world." In addition to our current portfolio of medicines for cancer and cardiovascular disease, Daiichi Sankyo is primarily focused on developing novel therapies for people with cancer as well as other diseases with high unmet medical needs. With more than 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 to realize our 2030 Vision to become an "Innovative Global Healthcare Company Contributing to the Sustainable Development of Society." 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