American Regent Introduces HydrALAZINE Hydrochloride Injection, USP; "AP" Rated and Therapeutically Equivalent to Apresoline®[1, 2]

HydrALAZINE Hydrochloride Injection, USP is supplied as a 1 mL single dose vial with a concentration of 20 mg/mL.

Melville, NY – July 1, 2021: American Regent announces the introduction and availability of HydrALAZINE Hydrochloride Injection, USP—"AP" Rated and therapeutically equivalent to Apresoline® [1,2]. HydrALAZINE is indicated for severe essential hypertension when the drug cannot be given orally or when there is an urgent need to lower blood pressure.

"An important part of our company's mission is to assist in mitigating shortages and ensuring supply of critical medications whenever possible. To that end, we are pleased to add HydrALAZINE Hydrochloride Injection to our robust line of products that are formulated, filled and finished at our US-based manufacturing facilities," stated Joann Gioia, Associate Vice President, Commercial Operations and National Accounts at American Regent, Inc.

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

HydrALAZINE Hydrochloride Injection, USP, is supplied as follows:

Pack NDC#	Strength	Supplied As	Shelf Pack
0517-0901-25	20 mg/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.

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=040136#31
2. Apresoline® is a registered trademark of Novartis Pharmaceuticals, Corp.

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A Daiichi Sankyo Group Company

HydrALAZINE Hydrochloride Injection, USP

For intravenous and intramuscular administration

INDICATIONS AND USAGE

Severe essential hypertension when the drug cannot be given orally or when there is an urgent need to lower blood pressure

IMPORTANT SAFETY INFORMATION

CONTRAINDICATIONS

Hypersensitivity to hydralazine; coronary artery disease; mitral valvular rheumatic heart disease.

WARNINGS

Hydralazine may produce a clinical picture simulating systemic lupus erythematosus, necessitating discontinuation unless the benefit-to-risk determination requires continued antihypertensive therapy with this drug. Symptoms and signs usually regress when the drug is discontinued but residua have been detected many years later.

PRECAUTIONS

General: Myocardial stimulation produced by hydralazine can cause anginal attacks and ECG changes of myocardial ischemia including myocardial infarction.
Use with caution in patients with suspected coronary artery disease or advanced renal damage.

Laboratory Tests: Complete blood counts and antinuclear antibody titer determinations are indicated before and periodically during prolonged therapy.
Blood dyscrasias have been reported. If such abnormalities develop, therapy should be discontinued.

Drug Interactions: MAO inhibitors; other antihypertensive drugs.

Pregnancy: *Teratogenic effects.* Pregnancy Category C:
There are no adequate and well-controlled studies in pregnant women. Hydralazine should be used during pregnancy only if the expected benefit justifies the potential risk to the fetus.

Nursing Mothers: Hydralazine has been shown to be excreted in breast milk.

Pediatric Use: Safety and effectiveness in pediatric patients have not been established.

ADVERSE REACTIONS

The following adverse reactions are not limited to:
Common: Headache, anorexia, nausea, vomiting, diarrhea, palpitations, tachycardia, angina pectoris.
Less Frequent: *Digestive:* constipation, paralytic ileus
Cardiovascular: hypotension, paradoxical pressor response, edema
Respiratory: dyspnea
Neurologic: peripheral neuritis; dizziness; tremors; muscle cramps; psychotic reactions characterized by depression, disorientation, or anxiety
Genitourinary: difficulty in urination
Hematologic: blood dyscrasias; lymphadenopathy; splenomegaly
Hypersensitive Reactions: rash, urticaria, pruritus, fever, chills, arthralgia, eosinophilia and rarely, hepatitis
Other: nasal congestion, flushing, lacrimation, conjunctivitis

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.

REF-1505 4/2020

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. 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 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.