For Immediate Release

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American Regent Announces the Availability of Dicyclomine Hydrochloride Injection, USP; AP rated and therapeutically equivalent to Bentyl®[1]*

Shirley, NY - American Regent today announced the introduction of Dicyclomine Hydrochloride Injection, USP. **Dicyclomine Hydrochloride Injection, USP is available for immediate shipment. Customers can order Dicyclomine Hydrochloride Injection, USP through their wholesaler/distributor or by contacting our Customer Support Group at 1-800-645-1706.**

Dicyclomine Hydrochloride Injection is indicated for the treatment of patients with functional bowel/irritable bowel syndrome.

Dicyclomine Hydrochloride Injection, USP is supplied as follows:

NDC#	Strength	Supplied As	Shelf Pack
0517-1980-05	20 mg/2 mL (10 mg/mL)	2 mL single dose vial	5

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

Dicyclomine Hydrochloride Injection, USP

For intramuscular use

INDICATIONS AND USAGE
Dicyclomine hydrochloride injection is indicated for the treatment of patients with functional bowel/irritable bowel syndrome.

IMPORTANT SAFETY INFORMATION

CONTRAINDICATIONS
Infants less than 6 months of age; Nursing mothers; and in patients with: unstable cardiovascular status in acute hemorrhage, myasthenia gravis, glaucoma, obstructive uropathy, obstructive disease of the gastrointestinal tract, severe ulcerative colitis, reflux esophagitis.

WARNINGS AND PRECAUTIONS

For Intramuscular injection only; should not be administered by any other route. Intravenous injection may result in thrombosis or thrombophlebitis and injection site reactions.

Cardiovascular conditions: worsening of conditions

Peripheral and central nervous system**:** heat prostration can occur with drug use (fever and heat stroke due to decreased sweating). It should also be used cautiously in patients with fever. If symptoms occur, drug should be discontinued and supportive measures instituted. Because of the inhibitory effect on muscarinic receptors within the autonomic nervous system, caution should be taken in patients with autonomic neuropathy.

Dicyclomine hydrochloride may produce drowsiness, dizziness or blurred vision. The patient should be warned not to engage in activities requiring mental alertness, such as operating a motor vehicle or other machinery or performing hazardous work while taking dicyclomine hydrochloride

Psychosis and delirium have been reported in patients sensitive to anticholinergic drugs (such as elderly patients and/or in patients with mental illness).

Myasthenia Gravis: overdose may lead to muscular weakness and paralysis. Dicyclomine hydrochloride should be given to patients with myasthenia gravis only to reduce adverse muscarinic effects of an anticholinesterase

Incomplete intestinal obstruction: diarrhea may be an early symptom especially in patients with ileostomy or colostomy. Treatment with dicyclomine hydrochloride would be inappropriate and possibly fatal

Salmonella dysenteric patients: due to risk of toxic megacolon

Ulcerative colitis: dicyclomine hydrochloride should be used with caution in these patients; large doses may suppress intestinal motility or aggravate the serious complications of toxic megacolon

Prostatic hypertrophy: dicyclomine hydrochloride should be used with caution in these patients; may lead to urinary retention

Hepatic and Renal Disease: should be used with caution

Geriatric: use with caution in elderly who may be more susceptible to dicyclomine hydrochloride's adverse events

ADVERSE REACTIONS

The most serious adverse reactions include cardiovascular and central nervous system symptoms. The most common adverse reactions (>5% of patients) are dizziness, dry mouth, vision blurred, nausea, somnolence, asthenia and nervousness.

USE IN SPECIFIC POPULATIONS

Pregnancy: use only if clearly needed

Nursing Mothers: Dicyclomine hydrochloride is contraindicated in women who are breastfeeding. Dicyclomine is excreted in human milk

Pediatric Use: Safety and effectiveness not established. Contraindicated in infants less than 6 months of age

Geriatric Use: Because elderly patients are more likely to have decreased renal function, care should be taken in dose selection, and it may be useful to monitor renal function

Hepatic and Renal Impairment: Caution must be taken with patients with impaired hepatic and renal function

Reference: 1. Approved Drug Products with Therapeutic Equivalence Evaluations. https://www.accessdata.fda.gov/scripts/cder/ob/results_product.cfm?Appl_Type=A&Appl_No=208353 Accessed June 6, 2017.

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

ADEs may also be reported to the FDA
at 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)

1-877-845-6371
(Available outside of normal business hours)

About American Regent

American Regent is a leader in the development, manufacturing and sales of generic and branded IV iron medications. With a history of 50 years in generic specialty injectables, American Regent has sales approaching one billion dollars from products manufactured in our facilities in the United States. American Regent strives for continuous improvement to bring to market high quality innovative medications to meet unmet medical needs, and produces high quality accessible generic medications covering a wide array of therapeutic areas. American Regent is a member of the Daiichi Sankyo Group; and is headquartered in Shirley, NY.

For more information, please visit 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. 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.