For Immediate Release

May 15, 2017

Harsher Singh
Vice President and Chief Commercial Officer
American Regent, Inc.
Ph: 631-924-4000
corpcommunications@americanregent.com

American Regent Announces the Availability of Hydroxyzine HCl Injection, USP; AP rated and therapeutically equivalent to Vistaril®[1]*

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

- Each mL contains: Hydroxyzine HCl 25 mg, Benzyl Alcohol 0.9 %, and Water for Injection q.s. pH adjusted with Sodium Hydroxide and/or Hydrochloric Acid

- Each mL contains: Hydroxyzine HCl 50 mg, Benzyl Alcohol 0.9 %, and Water for Injection q.s. pH adjusted with Sodium Hydroxide and/or Hydrochloric Acid

Hydroxyzine HCl Injection is supplied as three different single dose vials as follows:

NDC#	Strength	Supplied As	Shelf Pack
0517-4201-25	25 mg/mL	1 mL vial	25
0517-5601-25	50 mg/mL	1mL vial	25
0517-5602-25	50 mg/mL	2 mL vial	25

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

For Intramuscular Use Only

INDICATIONS AND USAGE
Hydroxyzine hydrochloride intramuscular solution is useful in treating the following types of patients when intramuscular administration is indicated:

1. The acutely disturbed or hysterical patient.
2. The acute or chronic alcoholic with anxiety withdrawal symptoms or delirium tremens.
3. As pre-and postoperative and pre-and postpartum adjunctive medication to permit reduction in narcotic dosage, allay anxiety and control emesis.

IMPORTANT SAFETY INFORMATION

CONTRAINDICATIONS
Hydroxyzine hydrochloride intramuscular solution is intended only for intramuscular administration and should not, under any circumstances, be injected subcutaneously, intra-arterially or intravenously.

Hydroxyzine is contraindicated in patients with a prolonged QT interval. This drug is contraindicated for patients who have shown a previous hypersensitivity to it.

Because clinical data in human beings are inadequate to establish safety in early pregnancy, hydroxyzine is contraindicated in early pregnancy.

WARNINGS
Tissue damage: Intramuscular hydroxyzine hydrochloride may result in severe injection site reactions (including extensive tissue damage, necrosis and gangrene) requiring surgical intervention (including debridement, skin grafting and amputation).

PRECAUTIONS
THE POTENTIATING ACTION OF HYDROXYZINE MUST BE CONSIDERED WHEN THE DRUG IS USED IN CONJUNCTION WITH CENTRAL NERVOUS SYSTEM DEPRESSANTS SUCH AS NARCOTICS, BARBITURATES AND ALCOHOL. Rarely, cardiac arrests and death have been reported in association with the combined use of hydroxyzine hydrochloride intramuscularly and other CNS depressants. Therefore, when central nervous system depressants are administered concomitantly with hydroxyzine their dosage should be reduced up to 50 percent.

HYDROXYZINE MAY POTENTIATE NARCOTICS AND BARBITURATES, so their use in preanesthetic adjunctive therapy should be modified on an individual basis.
When hydroxyzine is used preoperatively or prepartum, narcotic requirements may be reduced as much as 50 percent. Meperidine should be used with great caution and in reduced dosage in patients who are receiving other pre-and/or postoperative medications and in whom there is a risk of respiratory depression, hypotension, and profound sedation or coma occurring. Before using any medications concomitant with hydroxyzine, the manufacturer's prescribing information should be read carefully.

Since drowsiness may occur with the use of this drug, patients should be warned of this possibility and cautioned against driving a car or operating dangerous machinery while taking this drug.

CASES OF QT PROLONGATION AND TORSADE DE POINTES HAVE BEEN REPORTED DURING POSTMARKETING USE OF HYDROXYZINE. The majority of reports occurred in patients with other risk factors for QT prolongation or Torsade de Pointes (pre-existing heart disease, electrolyte imbalances or concomitant arrhythmogenic drug use). Therefore, hydroxyzine should be used with caution in patients with risk factors for QT prolongation, congenital long QT syndrome, a family history of long QT syndrome, other conditions that predispose to QT prolongation and ventricular arrhythmia, as well as recent myocardial infarction, uncompensated heart failure, and bradyarrhythmias.
Caution is recommended during the concomitant use of drugs known to prolong the QT interval.

Acute Generalized Exanthematous Pustulosis (AGEP)
Hydroxyzine may rarely cause acute generalized exanthematous pustulosis (AGEP), a serious skin reaction characterized by fever and numerous small, superficial, nonfollicular, sterile pustules, arising within large areas of edematous erythema. Inform patients about the signs of AGEP. Discontinue hydroxyzine at the first appearance of a skin rash, worsening of pre-existing skin reactions which hydroxyzine may be used to treat, or any other sign of hypersensitivity. If signs or symptoms suggest AGEP, use of hydroxyzine should not be resumed and alternative therapy should be considered. Avoid cetirizine or levocetirizine in patients who have experienced AGEP or other hypersensitivity reactions with hydroxyzine, due to the risk of cross-sensitivity.

ADVERSE REACTIONS
Therapeutic doses of hydroxyzine seldom produce impairment of mental alertness. However, drowsiness may occur; if so, it is usually transitory and may disappear in a few days of continued therapy or upon reduction of the dose. Dryness of the mouth may be encountered at higher doses.
Involuntary motor activity, including rare instances of tremor and convulsions, has been reported, usually with doses considerably higher than those recommended. Hydroxyzine hydrochloride is associated with Acute Generalized Exanthematous Pustulosis (AGEP) in post marketing reports.

*Vistaril is a trademark of Pfizer, Inc.

Reference: 1. Approved Drug Products with Therapeutic Equivalence Evaluations. http://www.accessdata.fda.gov/scripts/cder/ob/default.cfm Updated January 25, 2017. Accessed March 17, 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

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.

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