



For Immediate Release

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Droperidol Injection, USP is supplied as a 2 mL single dose vial in a shelf pack of 25. The strength is 5 mg/2 mL.

American Regent Re-introduces Droperidol Injection, USP; AP Rated and Therapeutically Equivalent to Inapsine®1*

Shirley, NY - American Regent, Inc. today announced the re-introduction of Droperidol Injection, USP.

Droperidol Injection, USP is indicated to reduce the incidence of nausea and vomiting associated with surgical and diagnostic procedures. "American Regent is pleased to be able to bring this critical drug back to the market, and to offer health care providers another option to help treat nausea and vomiting." said Harsher Singh, Vice President and Chief Commercial Officer at American Regent, Inc.

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

Droperidol Injection, USP is supplied as follows:

Table with 4 columns: NDC#, Strength, Supplied As, Shelf Pack. Row 1: 0517-9702-01, 5 mg/2mL (2.5 mg/mL), 2 mL Single Dose Vial, 25

*Inapsine® is a trademark of Akorn Inc.

See the following Important Safety Information, including BOXED WARNING, in addition to the Full Prescribing Information.

For additional information, please visit americanregent.com.

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=072123. Accessed April 5, 2018.

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A Daiichi Sankyo Group Company

**DROPERIDOL INJECTION, USP**

For IV or IM Use Only

INDICATIONS AND USAGE

Droperidol Injection is indicated to reduce the incidence of nausea and vomiting associated with surgical and diagnostic procedures.

IMPORTANT SAFETY INFORMATION**WARNING**

Cases of QT prolongation and/or torsade de pointes have been reported in patients receiving droperidol at doses at or below recommended doses. Some cases have occurred in patients with no known risk factors for QT prolongation and some cases have been fatal.

Due to its potential for serious proarrhythmic effects and death, droperidol should be reserved for use in the treatment of patients who fail to show an acceptable response to other adequate treatments, either because of insufficient effectiveness or the inability to achieve an effective dose due to intolerable adverse effects from those drugs.

Cases of QT prolongation and serious arrhythmias (e.g., torsade de pointes) have been reported in patients treated with droperidol. Based on these reports, all patients should undergo a 12-lead ECG prior to administration of droperidol to determine if a prolonged QT interval (i.e., QTc greater than 440 msec for males or 450 msec for females) is present. If there is a prolonged QT interval, droperidol should NOT be administered. For patients in whom the potential benefit of droperidol treatment is felt to outweigh the risks of potentially serious arrhythmias, ECG monitoring should be performed prior to treatment and continued for 2-3 hours after completing treatment to monitor for arrhythmias.

Droperidol is contraindicated in patients with known or suspected QT prolongation, including patients with congenital long QT syndrome.

Droperidol should be administered with extreme caution to patients who may be at risk for development of prolonged QT syndrome (e.g., congestive heart failure, bradycardia, use of a diuretic, cardiac hypertrophy, hypokalemia, hypomagnesemia, or administration of other drugs known to increase the QT interval). Other risk factors may include age over 65 years, alcohol abuse, and use of agents such as benzodiazepines, volatile anesthetics, and IV opiates.

Droperidol should be initiated at a low dose and adjusted upward, with caution, as needed to achieve the desired effect.

**CONTRAINDICATIONS**

Droperidol is contraindicated in patients with known or suspected QT prolongation.

Droperidol is contraindicated in patients with known hypersensitivity to the drug.

Droperidol is not recommended for any use other than for the treatment of perioperative nausea and vomiting in patients for whom other treatments are ineffective or inappropriate.

WARNINGS

Droperidol should be administered with extreme caution in the presence of risk factors for development of prolonged QT syndrome, such as: 1) clinically significant bradycardia, 2) any clinically significant cardiac disease, 3) treatment with Class I and Class III antiarrhythmics, 4) treatment with monoamine oxidase inhibitors, 5) concomitant treatment with other drug products known to prolong the QT interval and 6) electrolyte imbalance, in particular hypokalemia and hypomagnesemia, or concomitant treatment with drugs that may cause electrolyte imbalance.

Effects on Cardiac Conduction: A dose-dependent prolongation of the QT interval was observed within 10 minutes of droperidol administration in a study of 40 patients without known cardiac disease who underwent extracranial head and neck surgery.

Cases of QT prolongation and serious arrhythmias (e.g., torsade de pointes, ventricular arrhythmias, cardiac arrest, and death) have been observed during post-marketing treatment with droperidol.

For patients in whom the potential benefit of droperidol treatment is felt to outweigh the risks of potentially serious arrhythmias, ECG monitoring should be performed prior to treatment and continued for 2-3 hours after completing treatment to monitor for arrhythmias.

FLUIDS AND OTHER COUNTERMEASURES TO MANAGE HYPOTENSION SHOULD BE READILY AVAILABLE.

Patients who have received droperidol should have appropriate surveillance.

It is recommended that opioids, when required, initially be used in reduced doses.

Very rare reports of neuroleptic malignant syndrome have occurred in patients who have received droperidol.

Since it may be difficult to distinguish neuroleptic malignant syndrome from malignant hyperpyrexia in the perioperative period, prompt treatment with dantrolene should be considered if increases in temperature, heart rate or carbon dioxide production occur.



PRECAUTIONS

General: The initial dose of droperidol should be appropriately reduced in elderly, debilitated and other poor-risk patients.

The effect of the initial dose should be considered in determining incremental doses.

Droperidol can also alter circulation and may decrease pulmonary arterial pressure. Vital signs and ECG should be monitored routinely.

When the EEG is used for postoperative monitoring, it may be found that the EEG pattern returns to normal slowly.

Impaired Hepatic or Renal Function: Droperidol should be administered with caution to patients with liver and kidney dysfunction because of the importance of these organs in the metabolism and excretion of drugs.

Pheochromocytoma: In patients with diagnosed/suspected pheochromocytoma, severe hypertension and tachycardia have been observed after the administration of droperidol.

Drug Interactions:

Potentially Arrhythmogenic Agents: Any drug known to have the potential to prolong the QT interval should not be used together with droperidol.

Caution should be used when patients are taking concomitant drugs known to induce hypokalemia or hypomagnesemia as they may precipitate QT prolongation and interact with droperidol.

CNS Depressant Drugs: Other CNS depressant drugs have additive or potentiating effects with droperidol. When patients have received such drugs, the dose of droperidol required will be less than usual.

Pregnancy: Category C.

There are no adequate and well-controlled studies in pregnant women. Droperidol should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus.

Labor and Delivery: There are insufficient data to support the use of droperidol in labor and delivery.

Nursing Mothers: It is not known whether droperidol is excreted in human milk. Because many drugs are excreted in human milk, caution should be exercised when droperidol is administered to a nursing mother.

Pediatric Use: The safety of droperidol in children younger than two years of age has not been established.



ADVERSE REACTIONS

QT interval prolongation, torsade de pointes, cardiac arrest, and ventricular tachycardia have been reported in patients treated with droperidol. Some of these cases were associated with death. Some cases occurred in patients with no known risk factors, and some were associated with droperidol doses at or below recommended doses.

Physicians should be alert to palpitations, syncope, or other symptoms suggestive of episodes of irregular cardiac rhythm in patients taking droperidol and promptly evaluate such cases. The most common somatic adverse reactions reported to occur with droperidol are mild to moderate hypotension and tachycardia. If hypotension occurs and is severe or persists, the possibility of hypovolemia should be considered and managed with appropriate parenteral fluid therapy.

The most common behavioral adverse effects of droperidol include dysphoria, postoperative drowsiness, restlessness, hyperactivity and anxiety, which can either be the result of an inadequate dosage or of an adverse drug reaction.

Postoperative hallucinatory episodes (sometimes associated with transient periods of mental depression) have also been reported.

Other less common reported adverse reactions include anaphylaxis, dizziness, chills and/or shivering, laryngospasm and bronchospasm.

Elevated blood pressure, with or without pre-existing hypertension, has been reported following administration of droperidol combined with fentanyl citrate or other parenteral analgesics.

OVERDOSAGE

Manifestations: The manifestations of droperidol overdose are an extension of its pharmacologic actions and may include QT prolongation and serious arrhythmias.

Treatment: In the presence of hypoventilation or apnea, oxygen should be administered and respiration should be assisted or controlled as indicated. A patent airway must be maintained. The patient should be carefully observed for 24 hours; body warmth and adequate fluid intake should be maintained.

If hypotension occurs and is severe or persists, the possibility of hypovolemia should be considered and managed with appropriate parenteral fluid therapy.

If significant extrapyramidal reactions occur in the context of an overdose, an anticholinergic should be administered.

For additional safety information, including BOXED WARNING, please see Full Prescribing Information.



**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
at 1.800.FDA.1088 or to
www.fda.gov/MedWatch

Drug Information:
1.888.354.4855
(9:00am–5:00pm Eastern Time, Monday–Friday)

**For urgent drug information outside of normal
business hours, assistance is available at:**
1.877.845.6371

About American Regent, Inc.

American Regent is a leader in the development, manufacturing and sales of generic and branded IV products. With a history of 50 years in generic specialty injectables, American Regent has sales approaching one billion dollars.

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 <https://www.americanregent.com/>.

About Daiichi Sankyo

Daiichi Sankyo is a global pharmaceutical company with corporate origins in Japan. We provide innovative products and services in more than 20 countries around the world. With more than 100 years of scientific expertise, our company draws upon a rich legacy of innovation and a robust pipeline of promising new medicines to help patients.

Through the outstanding knowledge and commitment of our 15,000 employees worldwide, we create innovative new and generic medicines, and new methods of drug discovery and delivery. We share a passion for innovation, as well as compassion for the patients around the world who are in need of our medicines.

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.