

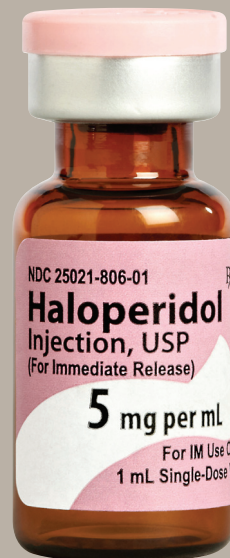
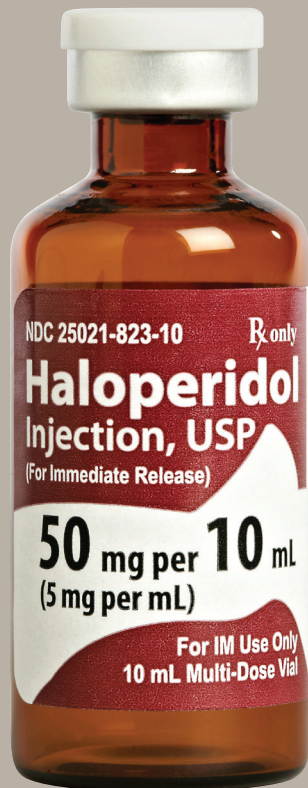


SAGENT Pharmaceuticals™

HALOPERIDOL Injection, USP

Consider these SAGENT benefits:

- Available in:
 - 5 mg per mL single-dose vials*
 - 50 mg per 10 mL multi-dose vials
- LATEX-FREE
- Discover **PreventIV Measures**™ packaging features:
 - Easy-to-read drug name and dosage strength
 - Bar codes included on the vials and cartons for ease of scanning
 - Unique label designEnhanced packaging and labeling designed to promote safety and help reduce medication errors



*Preservative-free
Please see full prescribing information for HALOPERIDOL Injection, USP, enclosed.



Discover Injectables Excellence™

HALOPERIDOL Injection, USP



Innovator Product Name: HALDOL® (HALDOL is a registered trademark of Johnson & Johnson Corporation.)

NDC Number	Description	Strength	Fill Volume	Concentration	Closure	Unit of Sale	Bar Coded
25021-806-01	Amber Vial	5 mg*	1 mL	5 mg per mL	13 mm	10 Vials	✓
25021-823-10	Amber Vial	50 mg	10 mL	5 mg per mL	13 mm	1 Vial	✓

*Preservative-free

These SAGENT products meet stringent FDA requirements and are AP rated and LATEX-FREE.

To order, or for more information about discovering Injectables Excellence™ with SAGENT, contact your sales representative, call 1-866-625-1618 or visit www.SagentPharma.com.

Listening. Responding. Delivering. That's Injectables Excellence.™ That's SAGENT Pharmaceuticals.

HALOPERIDOL Injection, USP

INDICATIONS

Haloperidol Injection, USP is indicated for use in the treatment of schizophrenia and for the control of tics and vocal utterances of Tourette's Disorder.

IMPORTANT SAFETY INFORMATION

WARNING

Increased Mortality in Elderly Patients with Dementia-Related Psychosis

Elderly patients with dementia-related psychosis treated with antipsychotic drugs are at an increased risk of death. Analyses of seventeen placebo-controlled trials (modal duration of 10 weeks), largely in patients taking atypical antipsychotic drugs, revealed a risk of death in drug-treated patients of between 1.6 to 1.7 times the risk of death in placebo-treated patients. Over the course of a typical 10-week controlled trial, the rate of death in drug-treated patients was about 4.5%, compared to a rate of about 2.6% in the placebo group. Although the causes of death were varied, most of the deaths appeared to be either cardiovascular (e.g., heart failure, sudden death) or infectious (e.g., pneumonia) in nature. Observational studies suggest that, similar to atypical antipsychotic drugs, treatment with conventional antipsychotic drugs may increase mortality. The extent to which the findings of increased mortality in observational studies may be attributed to the antipsychotic drug as opposed to some characteristic(s) of the patients is not clear. Haloperidol injection is not approved for the treatment of patients with dementia-related psychosis (see WARNINGS).

CONTRAINDICATIONS

Haloperidol injection is contraindicated in severe toxic central nervous system depression or comatose states from any cause and in individuals who are hypersensitive to this drug or have Parkinson's disease.

WARNINGS

- Elderly patients with dementia-related psychosis treated with antipsychotic drugs are at an increased risk of death. Haloperidol injection is not approved for the treatment of patients with dementia-related psychosis (see BOXED WARNING).
- Cases of sudden death, QT-prolongation, and Torsades de Pointes have been reported in patients receiving haloperidol. Higher than recommended doses of any formulation and intravenous administration of haloperidol appear to be associated with a higher risk of QT-prolongation and Torsades de Pointes. Particular caution is advised in treating patients with other QT-prolonging conditions (including electrolyte imbalance [particularly hypokalemia and hypomagnesemia], drugs known to prolong QT, underlying cardiac abnormalities, hypothyroidism, and familial long QT-syndrome). HALOPERIDOL INJECTION IS NOT APPROVED FOR INTRAVENOUS ADMINISTRATION. If haloperidol injection is administered intravenously, the ECG should be monitored for QT prolongation and arrhythmias.
- Tardive dyskinesia, a syndrome consisting of potentially irreversible, involuntary, dyskinetic movements, may develop in patients treated with antipsychotic drugs. Both the risk of developing tardive dyskinesia and the likelihood that it will become irreversible are believed to increase as the duration of treatment and the total cumulative dose of antipsychotic drugs administered to the patient increase. There is no known treatment for established cases of tardive dyskinesia, although the syndrome may remit, partially or completely, if antipsychotic treatment is withdrawn.
- A potentially fatal symptom complex sometimes referred to as Neuroleptic Malignant Syndrome (NMS) has been reported in association with antipsychotic drugs. Clinical manifestations of NMS are hyperpyrexia, muscle rigidity, altered mental status (including catatonic signs) and evidence of autonomic instability (irregular pulse or blood pressure, tachycardia, diaphoresis, and cardiac dysrhythmias). The management of NMS should include 1) immediate discontinuation of antipsychotic drugs and other drugs not essential to concurrent therapy, 2) intensive symptomatic treatment and medical monitoring, and 3) treatment of any concomitant serious medical problems for which specific treatments are available. Hyperpyrexia and heat stroke, not associated with the above symptom complex, have also been reported with haloperidol.
- There are no well controlled studies with haloperidol injection in pregnant women. There are reports, however, of cases of limb malformations observed following maternal use of haloperidol along with other drugs which have suspected teratogenic potential during the first trimester of pregnancy. Haloperidol should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus. Neonates exposed to antipsychotic drugs (including haloperidol) during the third semester of pregnancy are at risk for extrapyramidal and/or withdrawal symptoms following delivery.
- An encephalopathic syndrome (characterized by weakness, lethargy, fever, tremulousness and confusion, extrapyramidal symptoms, leukocytosis, elevated serum enzymes, BUN, and fasting blood sugar) followed by irreversible brain damage has occurred in a few patients treated with lithium plus haloperidol.

- A number of cases of bronchopneumonia, some fatal, have followed the use of antipsychotic drugs, including haloperidol.

PRECAUTIONS

- In clinical trial and/or postmarketing experience, events of leukopenia/neutropenia have been reported temporally related to antipsychotic agents, including haloperidol. Agranulocytosis has also been reported.
- Haloperidol injection should be administered cautiously to patients with severe cardiovascular disorders, because of the possibility of transient hypotension and/or precipitation of anginal pain.
- Haloperidol injection should be administered cautiously to patients receiving anticonvulsant medications, with a history of seizures, or with EEG abnormalities, because haloperidol may lower the convulsive threshold.
- Haloperidol injection should be administered cautiously to patients with known allergies, or with a history of allergic reactions to drugs.
- Haloperidol injection should be administered cautiously to patients receiving anticoagulants, since an isolated instance of interference occurred with the effects of one anticoagulant (phenindione).
- When haloperidol is used to control mania in cyclic disorders, there may be a rapid mood swing to depression.
- Severe neurotoxicity (rigidity, inability to walk or talk) may occur in patients with thyrotoxicosis who are also receiving antipsychotic medication, including haloperidol.
- If concomitant antiparkinson medication is required, it may have to be continued after haloperidol is discontinued because of the difference in excretion rates.
- Haloperidol may be capable of potentiating CNS depressants such as anesthetics, opiates and alcohol.
- It may be necessary to reduce the haloperidol dosage when it is used in combination with the metabolic inhibitors ketozonazole and paroxetine.
- Haloperidol is metabolized by several routes, including the glucuronidation and the cytochrome P450 enzyme system. Inhibition of these routes of metabolism by another drug may result in increased haloperidol concentration and potentially increase the risk of certain adverse events, including QT-prolongation.
- Haloperidol may impair the mental and/or physical abilities required for the performance of hazardous tasks such as operating machinery or driving a motor vehicle.
- The use of alcohol with this drug should be avoided due to possible additive effects and hypotension.
- No mutagenic potential was found in the Ames Salmonella microsomal activation assay.

ADVERSE REACTIONS

- Tachycardia, hypotension, and hypertension have been reported. QT prolongation and/or ventricular arrhythmias have also been reported, in addition to ECG pattern changes compatible with the polymorphous configuration of torsades de pointes.
- Extrapyramidal Symptoms (EPS) during the administration of haloperidol have been reported frequently, often during the first few days of treatment. EPS can be categorized generally as Parkinson-like symptoms, akathisia, or dystonia (including opisthotonos and oculogyric crisis).
- Some patients on maintenance treatment experience transient dyskinetic signs after abrupt withdrawal.
- Haloperidol has been associated with persistent dyskinesias.
- Tardive dyskinesia, a syndrome consisting of potentially irreversible, involuntary, dyskinetic movements, may appear in some patients on long-term therapy or may occur after drug therapy has been discontinued.
- Tardive dystonia, characterized by delayed onset of choreic or dystonic movements, often persistent, and having the potential of becoming irreversible, has been reported.

OVERDOSAGE

- In general, the symptoms of overdosage would be an exaggeration of known pharmacologic effects and adverse reactions, the most prominent of which would be: 1) severe extrapyramidal reactions, 2) hypotension, or 3) sedation. The patient would appear comatose with respiratory depression and hypotension which could be severe enough to produce a shock-like state.
- Since there is no specific antidote, treatment is primarily supportive.

You are encouraged to report negative side effects of prescription drugs to the FDA. Visit www.fda.gov/medwatch, or call 1-800-FDA-1088.

Please see full prescribing information for HALOPERIDOL Injection, USP.

LATEX-FREE = There is no natural rubber latex in the vial container closure or label adhesive in this SAGENT product.

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