FRESENIUS KABI

caring for life

Advancing medication safety

Simplist syringes help make it easier to minimize risk while enhancing efficiency.

We're committed to advancing medication safety across the continuum of care by providing the medications you need in a manufacturer prepared prefilled syringe that can help reduce the risk of preparation and administration errors.

Haloperidol Injection, USP

5 mg per 1 mL presentation now available in Simplist® ready-to-administer prefilled syringes.

- Ready-to-adminster
- Single unit dosing
- Manufacturer prepared
- 24-month shelf life

Simplist® Haloperidol Injection, USP.

WARNING

Increased Mortality in Elderly Patients with Dementia-Related Psychosis

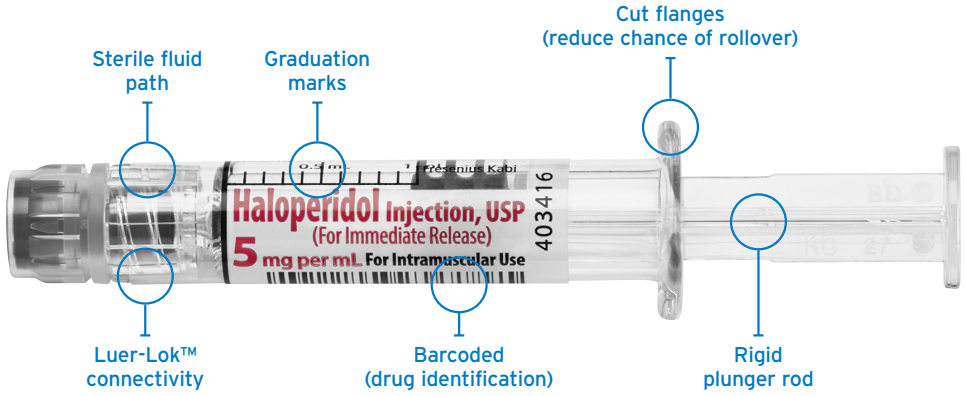
Elderly patients with dementia-related psychosis treated with antipsychotic drugs are at an increased risk of death. Analyses of seventeen placebo-controlled trials (modal duration of 10 weeks), largely in patients taking atypical antipsychotic drugs, revealed a risk of death in drug-treated patients 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, USP is not approved for the treatment of patients with dementia-related psychosis.

Please see Important Safety Information on the following page and go to products.fresenius-kabi.us/product-373.html for full prescribing information.

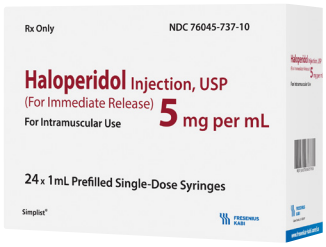
Please see package insert for full prescribing information.

1.888.386.1300 | www.fresenius-kabi.com/us

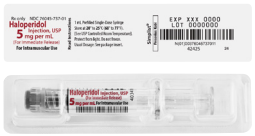
Haloperidol Injection, USP



Unit of Sale NDC Number (PK)	76045-737-10
Description	Single Dose Simplist® Syringe
Strength	5 mg per 1 mL
Concentration	5 mg per 1 mL
Fill Volume	1 mL
Unit of Sale	24
Bar Code	N(01)30376045737104



24-pack dimensions:
4.941" x 2.402" x 6.614"



Blister dimensions:
4.449" x 1.063"

INDICATIONS AND USE

Haloperidol Injection, USP (For Immediate Release) is indicated for intramuscular injection for use in the treatment of schizophrenia and for the control of tics and vocal utterances of Tourette's Disorder.

Haloperidol Injection, USP is not approved for the treatment of patients with dementia-related psychosis.

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, USP is not approved for the treatment of patients with dementia-related psychosis.

Haloperidol Injection, USP is contraindicated in patients with:
- Severe toxic central nervous system depression or comatose states from any cause
- Hypersensitivity to this drug – hypersensitivity reactions have included anaphylactic reaction and angioedema
- Parkinson's disease
- Dementia with Lewy bodies

Cardiovascular Effects: Cases of sudden death, QT-prolongation, and Torsades de Pointes have been reported in patients receiving haloperidol injection. Higher than recommended doses of any formulation and intravenous administration of haloperidol injection appear to be associated with a higher risk of QT-prolongation and Torsades de Pointes. HALOPERIDOL INJECTION IS NOT APPROVED FOR INTRAVENOUS ADMINISTRATION. Caution is advised when prescribing to a patient with QT-prolongation conditions or to patients receiving medications known to prolong the QT-interval or known to cause electrolyte imbalance.

Tardive Dyskinesia: 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.

Neuroleptic Malignant Syndrome (NMS): Clinical manifestations include hyperpyrexia, muscle rigidity, altered mental status (including catatonic signs) and evidence of autonomic instability (irregular pulse or blood pressure, tachycardia, diaphoresis, and cardiac dysrhythmias). Additional signs may include elevated creatine phosphokinase, myoglobinuria (rhabdomyolysis) and acute renal failure. Management of NMS should include immediate discontinuation of antipsychotic drugs and other drugs not essential to concurrent therapy.

Neurological Adverse Reactions in Patients with Parkinson's Disease or Dementia with Lewy Bodies: Patients with Parkinson's Disease or Dementia with Lewy Bodies are reported to have an increased sensitivity to antipsychotic medication. Manifestations of this increased sensitivity with haloperidol treatment include severe extrapyramidal symptoms, confusion, sedation, and falls. In addition, haloperidol may impair the antiparkinson effects of levodopa and other dopamine agonists.

Falls: Motor instability, somnolence, and orthostatic hypotension have been reported with the use of antipsychotics, including haloperidol. Assess the risk of falls when initiating antipsychotic treatment and recurrently for patients receiving repeated doses.

Combined use of Haloperidol and Lithium: Patients receiving such combined therapy should be monitored closely for early evidence of neurological toxicity and treatment discontinued promptly if such signs appear.

Leukopenia, Neutropenia, and Agranulocytosis: Discontinuation of Haloperidol injection should be considered at the first sign of a clinically significant decline in white blood cell count in the absence of other causative factors.

Withdrawal Emergent Dyskinesia: Some patients on maintenance treatment experience transient dyskinetic signs after abrupt withdrawal. Gradually withdraw use of haloperidol injection.

Pregnancy: There are no well controlled studies with haloperidol injection in pregnant women.

Nursing Mothers: Haloperidol is excreted in breast milk, infants should not be nursed during drug treatment with haloperidol.

Pediatric Use: Safety and effectiveness have not been established.

Geriatric Use: The prevalence of tardive dyskinesia appears to be highest among the elderly, especially elderly women. Lower doses are warranted in this population.

The most common adverse reactions (≥5%): extrapyramidal disorder, hyperkinesia, tremor, hypertonia, dystonia, and somnolence. **Adverse reactions occurring in ≥ 1% (Oral Haloperidol) also included:** constipation, dry mouth, salivary hypersecretion, and bradykinesia.

To report SUSPECTED ADVERSE REACTIONS, contact Fresenius Kabi USA, LLC, at 1-800-551-7176 option 5 or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

This Important Safety Information does not include all the information needed to use Haloperidol Injection, USP safely and effectively. Please see full prescribing information, including BOXED WARNING, for Haloperidol Injection, USP at www.fresenius-kabi.com/us.

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Ready-to-administer prefilled syringes

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To place an order, contact your Sales Representative or call Customer Service at 1.888.386.1300

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