Easy-to-see features right on the package

Packaging is InformatIV™
- Available in 5 mg per mL single-dose and 50 mg per 10 mL multi-dose vials
- Distinctive cap, label and carton colors help distinguish between different strengths

Labels and Cartons are DescriptIV™
- Easy-to-read drug name and strengths
- Unique label design for each presentation
- AP rated, bar coded and not made with natural rubber latex

HALOPERIDOL Injection, USP

Please see full prescribing information, including boxed warning, for HALOPERIDOL Injection, USP.
HALOPERIDOL Injection, USP

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

**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 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 2.5% 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 coma, states in which the patient is not expected to live, and is not recommended for pregnant patients (see WARNINGS and PRECAUTIONS). Treatment in the presence of comorbid serious medical conditions should be cautious (see PRECAUTIONS). Haloperidol Injection is contraindicated in severe extrapyramidal symptoms (see WARNINGS). Haloperidol Injection is contraindicated in the elderly with dementia because of the increased risk of death (see WARNINGS).

**WARNINGS**

• Haloperidol Injection is not approved for the treatment of patients with dementia-related psychosis (see WARNINGS).

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**PRECAUTIONS**

• There are no well-controlled studies with haloperidol injection in pregnant women. There are reports, however, of cases of congenital 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 trimester of pregnancy are at risk for extrapyramidal and/or withdrawal symptoms following delivery.

• 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 trimester of pregnancy are at risk for extrapyramidal and/or withdrawal symptoms following delivery. Haloperidol may be capable of potentiating CNS depressants such as anesthetics, opiates and alcohol. 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 AmesSalmonella 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. Extraeydriyal 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 dystonic signs after abrupt withdrawal. Haloperidol has been associated with persistent dystonias.

- Psychotic reactions to drugs.

- In general, the symptoms of overdose 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.

Please see full prescribing information for HALOPERIDOL Injection, USP.)

**OVERDOSAGE**

In general, the symptoms of overdose 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.
Haloperidol Injection, USP

(Amplettal) 5 mg/mL USP

Haloperidol Injection, USP is available as a sterile parenteral form for intramuscular injection in a 10 mL multi-dose vial, each mL containing 5 mg haloperidol (as the lactate) and an acidic pH to adjust the concentration between 3.0 to 3.8. Haloperidol Injection, USP is also available as a sterile parenteral form for intramuscular injection in a 5 mL, multidose vial, each mL containing 5 mg haloperidol (as the lactate) 5 mg methylparaben and 0.2% propylene glycol per mL (as preservatives), and 0.05% benzoic acid per mL (as preservatives and stabilizer).

INDICATIONS

The mechanism of action of haloperidol is not fully established. Haloperidol Injection, USP is indicated for use in the treatment of schizophrenia. It has been shown to be effective in the treatment of patients with dementia-related psychosis (see BOXED WARNING).

Contraindications

Cases of sudden death, QT-prolongation, and Torasemide de Pontes have been reported in patients taking haloperidol and it is important to use caution in patients taking other QT-prolonging agents or who have a history of QT-prolongation. Concomitant administration of haloperidol appears to be associated with a higher risk of QT-prolongation, especially in patients who are elderly, have heart disease, or are taking other QT-prolonging drugs. As both the prevalence of QT-prolongation and the severity of the adverse effect is increased in patients with QT-prolongation conditions (long QT- syndrome, heart failure, Brugada syndrome, short QT syndrome, etc.) the concomitant administration of haloperidol is not advised when prescribing to a patient with QT-prolongation conditions (long QT- syndrome, or have Parkinson's disease.

WARNINGS

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 compared to placebo-treated patients. The risk of death was elevated in clinical trials of elderly patients with dementia-related psychosis treated with antipsychotics. The cause of death was not systematically ascribed to antipsychotics in most cases. Since such evidence does not exclude the possibility of total death due to antipsychotics, such studies may be used to assist physicians in giving informed advice to patients and their families, and in counseling them on the risks involved.

Severe adverse reactions, including death, have been reported in elderly patients with dementia-related psychosis treated with antipsychotics. Haloperidol has not been approved for the treatment of patients with dementia-related psychosis (see BOXED WARNING). The effect of antipsychotic drugs on QTc interval has been demonstrated in post-marketing cases of torsades de pointes.

Tardive Dyskinesia

Cases of tardive dyskinesia (TD), QT-prolongation, and Torasemide de Pontes have been reported in patients taking haloperidol. The risk of developing TD is increased in patients treated with antipsychotics, including haloperidol. TD may be either cardiovascular (e.g., heart failure, sudden death) or infectious (e.g., pneumocystis pneumonia). TD usually develops after 6 to 12 months of antipsychotic treatment and has been reported to occur in as many as 20% of elderly patients treated with antipsychotics. TD may occur after a wide range of antipsychotic drug treatments, but TD appears to be more common with the traditional antipsychotic drugs, particularly those that are relatively low in their potency for blocking D2 receptors. TD is more common among the elderly, especially elderly women, in other patient populations it is most likely to minimize the occurrence of tardive dyskinesia. Haloperidol may be a risk factor for the development of tardive dyskinesia. The syndrome may remit, partially or completely, if antipsychotic treatment is withdrawn. The syndrome appears to be highest among the elderly, especially elderly women, it is not unknown.

The effect that symptomatic suppression has upon the long-term course of the syndrome is unknown. Treatment of TD usually requires discontinuation of antipsychotic drugs. Adjuvant treatments include cholinergic agents such as benztropine and amantadine. Other treatments such as SSRIs and anticholinergics have been used with mixed results.

The effectiveness of one anticoagulant (phenindione).

Since QT-prolongation has been observed during haloperidol treatment, it is recommended that adequate anticonvulsant therapy should be concomitantly maintained.

Neuroleptic Malignant Syndrome

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., pneumocystis pneumonia). Drugs known to prolong QT, including some antihypertensive, antihistaminic, antipsychotic, and antidepressant agents, appear to have the potential for inducing malignant ventricular arrhythmias. Haloperidol INJECTION, NOT APPROVED FOR INTRAVENOUS ADMINISTRATION; if haloperidol is administered intravenously, the ECG should be monitored for QT prolongation and arrhythmias.

Tardive Dyskinesia

A number of cases of sudden death, QT-prolongation, and Torasemide de Pontes have been reported in patients taking haloperidol. Concomitant administration of haloperidol appears to be associated with a higher risk of QT-prolongation, especially in patients who are elderly, have heart disease, or are taking other QT-prolonging drugs. In pharmacokinetic studies, mild to moderately increased haloperidol concentrations in combination with other drugs have been evaluated as described below.

Other

Neuroleptic Malignant Syndrome

Cases of sudden death, QT-prolongation, and Torasemide de Pontes have been reported in patients taking haloperidol. Concomitant administration of haloperidol appears to be associated with a higher risk of QT-prolongation, especially in patients who are elderly, have heart disease, or are taking other QT-prolonging drugs. In pharmacokinetic studies, mild to moderately increased haloperidol concentrations in combination with other drugs have been evaluated as described below.

Drug Interactions

When haloperidol is used to control mania in cyclic disorders, there may be a risk of increased toxicity from concomitant use of lithium. The concomitant use of antipsychotics other than haloperidol with lithium has not been systematically evaluated. In a study of 12 schizophrenic patients concomitantly treated with lithium and haloperidol, it was found that both drugs had a significant effect on the duration of mania. It was found that haloperidol produced a more rapid and larger effect on the duration of mania than lithium. However, the effect of haloperidol was less than the effect of lithium on the duration of mania.

Haloperidol plasma levels. When haloperidol is used to control mania in cyclic disorders, there may be a risk of increased toxicity from concomitant use of lithium. When haloperidol is used to control mania in cyclic disorders, there may be a risk of increased toxicity from concomitant use of lithium.
Tardive dystonia, not associated with the above syndrome, has also been reported. This syndrome may be masked.

Involuntary movements of tongue, face, mouth or jaw (e.g., protrusion of tongue, and in some patients appear irreversible. The syndrome is characterized by rhythmical}

Withdrawal Emergent Neurological Signs

Generally, patients receiving short-term therapy experience no problems with abrupt withdrawal. In certain cases, however, patients may develop transient dyskinetic signs after abrupt withdrawal. In certain

Dyskinesia

Dyskinesia

Clinical studies of haloperidol did not include sufficient numbers of subjects aged 65 and over to determine whether they responded differently from younger subjects. Other reported clinical experience and post-marketing data do not provide evidence of differences in overall safety or effectiveness of haloperidol between elderly and younger patients. However, the prevalence of tardive dyskinesia appears to be higher in elderly patients who are chronically medicated with the polypharmacy total tumor incidence; at 20 times the same daily dose there was a statistically significant increase in canine tumors. In rodents after chronic administration of antipsychotic drugs. Neither clinical studies nor post-marketing experience in humans have identified definitively what role, if any, haloperidol played in the outcome of the reported cases. Although it is not known whether antipsychotic drugs may cause a particular tumor type in an animal species, it is not known whether this would occur in humans. It is to be kept in mind that spontaneous tumors may occur in psychotic patients when treated with other antipsychotic drugs.

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