**Haloperidol**

**Indications**

- Haloperidol is indicated for the control of acute and initial outbursts of Tourette’s Disorder.
- Haloperidol injection, USP is available for this use.

**Contraindications**

- Haloperidol injection, USP is contraindicated in patients with a known hypersensitivity to haloperidol or any of its components.

**Warnings**

- Increased Mortality in Elderly Patients with Dementia-Related Psychosis

Elderly patients with dementia-related psychosis treated with antipsychotics are at an increased risk of death. Haloperidol injection, USP is not approved for the treatment of patients with dementia-related psychosis (see boxed warning).

- Haloperidol injection, USP is not approved for the treatment of children younger than 5 years of age (see boxed warning).

**Adverse Reactions**

- Neuroleptic Malignant Syndrome (NMS)

A potentially fatal symptom complex sometimes referred to as Neuroleptic Malignant Syndrome (NMS) has been reported in association with antipsychotic drug treatment (see boxed warning). The signs and symptoms of NMS can vary from mild to life-threatening (see boxed warning). In patients who develop NMS, the clinical presentation includes both serious extrapyramidal symptoms and serious medical complications including heat stroke and cardiovascular disorders (see boxed warning).

- Falls

- Motor instability, somnolence, and orthostatic hypotension may lead to falls, and may be maximal during the first few months of antipsychotic treatment, which patients are at particularly high risk (see boxed warning). In elderly patients, the incidence of antipsychotic treatment, which patients are at particularly high risk (see boxed warning). In elderly patients, the incidence of antipsychotic treatment, which patients are at particularly high risk (see boxed warning).

- Agranulocytosis has also been reported. Agranulocytosis has also been reported. Agranulocytosis has also been reported.

**Drug Interactions**

- Drug-drug interactions can be pharmacodynamic (i.e., changes in drug effects or toxicity) or pharmacokinetic (i.e., changes in drug levels).

**Pharmacokinetic Interactions**

- The use of alcohol with this drug should be avoided due to possible additive effects and hypotension.

**Pharmacodynamic Interactions**

- The effect of other antipsychotics on haloperidol is mediated by several routes, including the glutamatergic and the cytochrome P450 enzyme system. However, haloperidol is not known to appreciably increase the risk of developing these disorders, even in the absence of predisposing factors, particularly in elderly patients. Therefore, although not optimal, this study does not suggest the absence of a haloperidol-related risk.

**Usage in Pregnancy**

- There are no well-controlled studies with haloperidol in pregnant women. There are reports, however, of cases of limb abnormalities, among other potential risk to the fetus. Haloperidol and haloperidol plasma levels were decreased by a mean of 15% and mean scores on the Brief Psychiatric Rating Scale were increased from baseline to endpoint. In one study, haloperidol was administered as adjunctive therapy in patients who were receiving combined treatment with haloperidol with aripiprazole. In this study, there was no significant increase in the risk of developing tardive dyskinesia versus placebo. However, haloperidol is associated with an increased risk of death compared to placebo. Patients with tardive dyskinesia may experience the syndrome and thereby may possibly benefit from the discontinuation of antipsychotic treatment, itself, however, may suppress exacerbation of the syndrome and thereby may possibly benefit from the discontinuation of antipsychotic treatment, itself, however, may suppress exacerbation of the syndrome and thereby may possibly benefit from the discontinuation of antipsychotic treatment. The patient should be carefully monitored, since recurrences of NMS have been reported. Tardive Dyskinesia

Tardive Dyskinesia is a syndrome consisting of potentially irreversible, dose-related involuntary movements occurring in patients who develop movement disorders associated with antipsychotic drug treatment (see boxed warning). Haloperidol injection, USP is approved for the treatment of patients with schizophrenia.
Symptoms of dystonia, parkinsonism, cerebellar disorder, and a generalized or localized tremor, may occur in susceptible individuals in patients on long-term therapy or may occur in patients on high-dose therapy, especially females. The risk appears to be greater in elderly patients on high-dose therapy, especially females. The symptoms are persistent and in some patients appear irreversible. The syndrome is characterized by rhythmical involuntary movements of tongue, face, mouth or jaw (e.g., protrusion of tongue, puffing of cheeks, puckering of mouth, tongue thrusting), may be accompanied by involuntary movements of extremities and the head.

There is no known effective treatment for tardive dyskinesia, antiparkinson agents usually do not alleviate the symptoms of this syndrome. It is suggested that all antiparkinson agents be discontinued if these symptoms appear. It should be necessary to remit treatment, or increase the dosage of the agent, or switch to a different antiparkinson agent, if the syndrome progresses.

It has been reported that fine vermiform movements of the tongue may be an early sign of tardive dyskinesia and if the medication is discontinued at that time the full-blown syndrome may not develop.

Tardive Dyskinesia

Tardive dyskinesia, not associated with the above syndrome, has also been reported. Tardive dyskinesia is characterized by delayed onset of chronic antipsychotic movements, often persistent, and has the potential of becoming irreversible.

Other CNS Effects

Incontinence, insomnia, anxiety, euphoria, agitation, asthenia, depression, libido, headache, dyskinesia, grand mal seizures, exacerbation of psychotic symptoms including hallucinations, and catatonic-like movements which may be responsive to drugs withdrawal and/or treatment with anticholinergic drugs.

Body as a Whole

Neuropsychiatric malignant syndrome (NMS), hyperpyrexia, and heat stroke have been reported with haloperidol (see WARNINGS for further information concerning NMS).

Hematologic Effects

Reports have appeared citing the occurrence of dose and usually treated hemorrhagic thrombocytopenia in patients receiving haloperidol. However, evidence that higher doses of sulfonyl ureas, methylprednisolone USP, or isoprenaline hydrochloride USP is linked with the occurrence of platelet defects in patients treated with haloperidol has been reported; the drug may have to be discontinued in such cases.

Dystonia

Class Effect: Symptoms of dystonia, parkinsonism, cerebellar disorder, and a generalized or localized tremor, may occur in susceptible individuals in patients on high-dose therapy, especially females. The risk appears to be greater in elderly patients on high-dose therapy, especially females. The symptoms are persistent and in some patients appear irreversible. The syndrome is characterized by rhythmical involuntary movements of tongue, face, mouth or jaw (e.g., protrusion of tongue, puffing of cheeks, puckering of mouth, tongue thrusting), may be accompanied by involuntary movements of extremities and the head.

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