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

Tasks such as operating machinery or driving a motor vehicle. The ambulatory patient should be warned on

Haloperidol may impair the mental and/or physical abilities required for the performance of hazardous

A number of cases of bronchopneumonia, some fatal, have followed the use of antipsychotic drugs, appears.

causal relationship between these events and the concomitant administration of lithium and haloperidol

damage due to haloperidol, this drug should be used during pregnancy or in women likely to become

rodents given 2 to 20 times the usual maximum human dose of haloperidol by oral or parenteral routes

to the fetus.

Haloperidol should be used during pregnancy only if the potential benefit justifies the potential risk to

These complications have varied in severity; while in some cases symptoms have been self-limited, in

Non-teratogenic Effects

antipsychotic treatment and recurrently for patients on long-term antipsychotic therapy.

If a patient requires antipsychotic drug treatment after recovery from NMS, the potential reintroduction

There is no general agreement about specific pharmacological treatment regimens for uncomplicated

The management of NMS should include 1) immediate discontinuation of antipsychotic drugs and other

A potentially fatal symptom complex sometimes referred to as Neuroleptic Malignant Syndrome (NMS)

Both the risk of developing tardive dyskinesia and the likelihood that it will become irreversible are

Whether antipsychotic drug products differ in their potential to cause tardive dyskinesia is unknown.

to predict, at the inception of antipsychotic treatment, which patients are likely to develop the syndrome.

Tardive Dyskinesia

familial long QT-syndrome).

Elderly patients with dementia-related psychosis treated with antipsychotic drugs are at an increased

Increased Mortality in Elderly Patients with Dementia-Related Psychosis

Haloperidol is contraindicated in severe toxic central nervous system depression or comatose states

CONTRAINDICATIONS

do not become available for the treatment of patients with dementia-related psychosis (see WARNINGS).

CLINICAL PHARMACOLOGY

The precise mechanism of action is not clearly established.

DESCRIPTION

Haloperidol Tablets, USP

Each haloperidol tablet, USP contains one of the following equivalent haloperidol, USP 5 mg or 10 mg.

HALOPERIDOL- haloperidol tablet

FD & C Yellow #6 Aluminum Lake and D & C Red

WARNINGS

the therapeutic range. These particular side effects have not been observed in children treated with haloperidol.

Purpura, and hemolytic anemia. Hyperkalemia and hypomagnesemia have also been reported.

for the maintenance of control of acute exacerbation of mania or hypomania.

Disorders of the body, especially the extremities. The child with acute dystonia may also manifest

side effects: impulsive behaviors, hyperreflexia, and startle response. Several of these effects may be

Haloperidol is indicated for the control of tics and vocal utterances of Tourette's Disorder in children

Haloperidol is the first of the butyrophenone series of major tranquilizers. The chemical designation is

The value of haloperidol in the management of behavior disturbances in children has been documented in a

For further information about the description of tardive dyskinesia and its clinical detection, see WARNINGS.

If signs and symptoms of tardive dyskinesia appear in a patient on antipsychotics, drug discontinuation

Given these considerations, antipsychotic drugs should be prescribed in a manner that is most likely to

In order to predict, at the inception of antipsychotic treatment, which patients are likely to develop the syndrome,

The precise mechanism of action is not clearly established.

It is recommended that patients with a history of neuroleptic malignant syndrome be observed carefully during

Non-teratogenic Effects

The precise mechanism of action is not clearly established.

INDICATIONS AND USAGE

Haloperidol is effective in the short-term treatment of hyperactive children who show excessive

Haloperidol is indicated for the control of tics and vocal utterances of Tourette's Disorder in children

Haloperidol should be reserved for these two groups of children only after failure to

symptoms: impulsivity, difficulty sustaining attention, aggressivity, mood lability, and poor frustration

Neuroleptic Malignant Syndrome (NMS)

A potentially fatal symptom complex referred to as neuroleptic malignant syndrome (NMS) has been

It has been observed in children treated with haloperidol.

Teratogenic Effects

Lithium intoxication, hypokalemia, and hypocalcemia. The most common side effects were:

Non-teratogenic Effects

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Non-teratogenic Effects

The precise mechanism of action is not clearly established.
Dermatologic Reactions

Agranulocytosis has rarely been reported to have occurred with the use of haloperidol, and then only in association with other antipsychotic agents. The significance of these observations is difficult to assess.

Hematologic Effects

Neuroleptic malignant syndrome (NMS), hyperpyrexia and heat stroke have been reported with haloperidol. NMS is characterized by muscle rigidity, especially involving the trunk, dystonic movements, hyperthermia, autonomic dysfunction, disorientation, confusion, vertigo, grand mal seizures, exacerbation of psychotic symptoms including hallucinations and delusions.

Tardive dystonia, not associated with the above syndrome, has also been reported. Tardive dystonia is characterized by delayed onset of choreic or dystonic movements, may occur in clinical or subclinical states which may be responsive to drug withdrawal and/or treatment with cholinergic agonists or dopamine receptor agonists. Tardive dystonia is often persistent, and has the potential of becoming irreversible.

Tardive dyskinesia is a movement disorder that usually affects the face, tongue, and extremities and the trunk, and may be responsive to drug withdrawal and/or treatment with cholinergic agonists or dopamine receptor agonists. Tardive dyskinesia may occur in the absence of the syndrome described below under “TARDIVE DYSKINESIA” except for duration. It is not limited to be conclusive at this time.

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Cardiovascular Effects

Tachycardia, hypotension, and hypertension have been reported. QT prolongation and/or ventricular arrhythmias have been reported in patients treated with haloperidol. The risk of these effects may be increased when haloperidol is administered with CNS depressants such as anesthetics, opiates, and alcohol.

CNS Depressants

CNS depressants such as anesthetics, opiates, and alcohol, should not be used since haloperidol may block its vasopressor activity and paradoxical further lowering of the blood pressure may occur.

Disorders of Anaesthesia

Agranulocytosis has rarely been reported to have occurred with the use of haloperidol, and then only in association with other antipsychotic agents. The significance of these observations is difficult to assess.

Pregnancy

In clinical trials of haloperidol all 212 infants born to mothers who received haloperidol during pregnancy were assessed. Of these neonates, 5 required intensive care unit support and prolonged hospitalization. One case neonate had hypertonia, hypotonia, tremor, somnolence, respiratory distress and feeding disorder in these neonates.

Non-teratogenic Effects

Pregnancy:

Cases of sudden and unexpected death have been reported in association with the administration of these drugs and mammary tumorigenesis; the available evidence is considered too inconsistent to be conclusive at this time.

No statistically significant differences in incidences of total tumors or specific tumor types were noted. No statistically significant differences in the number of tumors were noted for females or males. Therefore, although no significant differences were noted for males, this study does not exclude the possibility that male rats may be sensitive to these effects.

Carcinogenicity studies using oral haloperidol were conducted in Wistar rats (dosed at up to 5 mg/kg daily for 24 months) and in Albino Swiss mice (dosed at up to 5 mg/kg daily for 18 months). In the rat study, male rats exhibited an increased incidence of mammary fibroadenoma. Male rats and female mice treated at 15 mg/kg daily exhibited an increased incidence of thyroid follicular cell adenoma/carcinoma. The significance of these findings is unknown.

Antipsychotic drugs elevate prolactin levels; the elevation persists during chronic administration.

When the prolactin levels of untreated psychotic patients were measured, prolactin levels were in the normal range. When these patients were treated with haloperidol, prolactin levels increased from baseline. In 5 other schizophrenic patients treated with haloperidol and rifampin, prolactin levels increased from baseline.

Drug interactions may enhance or diminish antipsychotic activity, depending on whether the antipsychotic agent is a dopamine receptor antagonist or a 5-HT2 receptor antagonist. If haloperidol is discontinued, the dosage of any concurrent medication should be reduced gradually in order to prevent symptoms of withdrawal and adverse effects occurring as a result of stopping treatment with haloperidol.

In patients with increased intracranial pressure, haloperidol may precipitate or exacerbate increased intracranial pressure.

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**Psychosis Disorders**

Leaving a hospital emergency room, mental hospital, mental institution, governmental, or a nursing home. Severe psychoses may also be treated with haloperidol.

**Contraindications**

Serious or unstable conditions, pregnancy, arhythmias, or myocardial infarction, or arrhythmias and uncontrolled hypertension.

**Adverse Effects**

This medication is associated with tremors, extrapyramidal reactions, and sleep disturbances. It may also cause dizziness, drowsiness, and excitement.

**DOSAGE AND ADMINISTRATION**

**Psychotic Disorders**

Severely disturbed psychotic patients may require higher doses. In severely disturbed, non-psychotic patients, 24 hours following the last parenteral dose.

**Severe Symptomatology**

The total dose may be divided, to be given b.i.d. or t.i.d. to 0.5 mg per day. If required, the dose should be increased by an increment of 0.5 mg at 5 to 7 day intervals until the desired therapeutic effect is obtained. (see chart below).

**Chronic or Resistant Patients**

The oral form should supplant the injectable as soon as practicable. In the absence of bioavailability information, the following recommendations apply to children between the ages of 3 and 12 years (weight range 15 to 40 kg). Haloperidol is not intended for children under 3 years old. Therapy should begin at the lowest dose possible (0.5 mg per day). If required, the dose should be increased by an increment of 0.5 mg at 5 to 7 day intervals for the desired therapeutic effect or clinical response. There is no evidence establishing a maximum effective dosage. There is little evidence that behavior improvement is further enhanced in dosages beyond 6 mg per day.

**Children**

Children, debilitated or geriatric patients, as well as those with a history of adverse reactions to previous response to other antipsychotic drugs, and any concomitant medication or disease state. To determine the initial dosage, consideration should be given to the patient's age, weight, sex, severity of illness, and response to other antipsychotic drugs. If required, the dose should be increased by an increment of 0.5 mg at 5 to 7 day intervals for the desired therapeutic effect or clinical response. There is no evidence establishing a maximum effective dosage. There is little evidence that behavior improvement is further enhanced in dosages beyond 6 mg per day.

**Maintenance Dosage**

Upon achieving a satisfactory therapeutic response, dosage should then be gradually reduced to the lowest dose possible (0.5 mg per day). If required, the dose should be increased by an increment of 0.5 mg at 5 to 7 day intervals for the desired therapeutic effect or clinical response. There is no evidence establishing a maximum effective dosage. There is little evidence that behavior improvement is further enhanced in dosages beyond 6 mg per day.

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**HALOPERIDOL**

5 mg Tablet

**Product Information**

- **Product Type**: HUMAN PRESCRIPTION DRUG
- **NDC**: 70518-1269 (NDC: 68382-079)

**Route of Administration**: ORAL

**Active Ingredient/Active Moiety**

- **Ingredient Name**: HALOPERIDOL (UNII: J6292F8L3D)
- **Basis of Strength**: HALOPERIDOL
- **Strength**: 5 mg

**Inactive Ingredients**

- CALCIUM STEARATE (UNII: 776XM7047L)
- D&C YELLOW NO. 10 (UNII: 35SW5USQ3G)
- DIBASIC CALCIUM PHOSPHATE DIHYDRATE (UNII: O7TSZ97GEP)
- FD&C BLUE NO. 1--ALUMINUM LAKE (UNII: J9EQA3S2JM)
- POVIDONE K30 (UNII: U725QWY32X)
- SODIUM STARCH GLYCOLATE TYPE A POTATO (UNII: 5856J3G2A2)
- STARCH, CORN (UNII: O8232NY3SJ)
- ALUMINUM OXIDE (UNII: LMI26O6933)

**Product Characteristics**

- **Color**: green (GREEN)
- **Score**: 2 pieces
- **Shape**: OVAL (CAPSULE)
- **Size**: 10mm
- **Flavor**: Imprint Code: ZC; 07

**Packaging**

- **# Item Code**: NDC:70518-1269-0
- **30 in 1 BLISTER PACK; Type 0: Not a Combination Product**

**Marketing Information**

- **Marketing Category**: ANDA
- **Application Number or Monograph Citation**: ANDA077580
- **Marketing Start Date**: 06/19/2018
- **Marketing End Date**: 06/19/2018

**Labeler**: REMEDYREPACK INC. (829572556)

**Revised**: 12/2019