For The Use of A Registered Medical Practitioner or A Hospital or A Laboratory

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Haloperidol Injection IP

AMERICAN

HPDOL

Injection **5 mg / 1 ml**

Composition:

Each ml. contains :

Haloperidol I.P.	5 mg.
Water for Injection I.P.	q.s.

DESCRIPTION:
Haloperidol is the first of the butyrophenone series of major antipsychotics. The chemical designation is 4-[4-(4-chlorophenyl)-4-hydroxypiperidin-1-yl]-1-(4-fluorophenyl) butan-1-one
Haloperidol Injection is available as a sterile parenteral form for intramuscular injection.
Each ml of clear, colourless sterile solution contains Haloperidol 5mg.

THERAPEUTIC INDICATIONS: Haloperidol Injection is indicated in adult patients for:
- Rapid control of severe acute psychomotor agitation associated with psychotic disorder or manic episodes of bipolar I disorder when oral therapy is not appropriate.
- Acute treatment of delirium when non-pharmacological treatments have failed.
- Treatment of mild to moderate chorea in Huntington's disease, when other medicinal products are ineffective or not tolerated, and oral therapy is not appropriate.
- Single or combination prophylaxis in patients at moderate to high risk of postoperative nausea and vomiting, when other medicinal products are ineffective or not tolerated.
- Combination treatment of postoperative nausea and vomiting when other medicinal products are ineffective or not tolerated.

DOSAGE AND METHOD OF ADMINISTRATION:
Dosage:
Adults: A low initial dose is recommended and this must be adjusted according to the patient's response in order to determine the minimal effective dose.

Haloperidol dose recommendations for adults aged 18 years and above -
Rapid control of severe acute psychomotor agitation associated with psychotic disorder or manic episodes of bipolar I disorder when oral therapy is not appropriate
- 5 mg intramuscularly.
- May be repeated hourly until sufficient symptom control is achieved.
- In the majority of patients, doses of up to 15 mg/day are sufficient. The maximum dose is 20 mg/day.

Acute treatment of delirium when non-pharmacological treatments have failed
- 1 to 10 mg intramuscularly.

Treatment should be started at the lowest possible dose, and the dose should be adjusted in increments at 2- to 4-hour intervals if agitation continues, up to a maximum of 10 mg/day.

Treatment of mild to moderate chorea in Huntington's disease, when other medicinal products are ineffective or not tolerated, and oral therapy is not appropriate
- 2 to 5 mg intramuscularly.
- May be repeated hourly until sufficient symptom control is achieved or up to a maximum of 10 mg/day.

Single or combination prophylaxis in patients at moderate to high risk of postoperative nausea and vomiting, when other medicinal products are ineffective or not tolerated
- 1 to 2 mg intramuscularly, at induction or 30 minutes before the end of anaesthesia.

Combination treatment of postoperative nausea and vomiting when other medicinal products are ineffective or not tolerated
1 to 2 mg intramuscularly.

Treatment withdrawal: Gradual withdrawal of haloperidol is advisable.

Special populations:
Elderly: The recommended initial haloperidol dose in elderly patients is half the lowest adult dose. Further doses may be administered and adjusted according to the patient's response. Careful and gradual dose up-titration in elderly patients is recommended.
The maximum dose is 5 mg/day.
Doses above 5 mg/day should only be considered in patients who have tolerated higher doses and after reassessment of the patient's individual benefit-risk profile.

Paediatric population: The safety and efficacy of haloperidol solution for injection in children and adolescents below 18 years of age have not been established.

Method for administration: Haloperidol solution for injection is recommended for intramuscular administration only.

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.

SPECIAL WARNINGS AND PRECAUTIONS FOR USE:
Increased mortality in elderly people with dementia: Elderly patients with dementia-related psychosis treated with antipsychotics are at an increased risk of death. Haloperidol solution for injection is not indicated for the treatment of dementia-related behavioural disturbances.

Cardiovascular effects: QTc prolongation and/or ventricular arrhythmias, in addition to sudden death, have been reported with haloperidol. The risk of these events appears to increase with high doses, high plasma concentrations, in predisposed patients or with parenteral use, particularly intravenous administration.
Caution is advised in patients with bradycardia, cardiac disease, family history of QTc prolongation or history of heavy alcohol exposure. Caution is also required in patients with potentially high plasma concentrations.
Tachycardia and hypotension (including orthostatic hypotension) have also been reported. Caution is recommended when haloperidol is administered to patients manifesting hypotension or orthostatic hypotension.

Cerebrovascular events: In randomised, placebo-controlled clinical studies in the dementia population, there was an approximately 3-fold increased risk of cerebrovascular adverse events with some atypical antipsychotics. Haloperidol must be used with caution in patients with risk factors for stroke.
Neuroleptic malignant syndrome
Tardive dyskinesia
Extrapyramidal symptoms
Seizures/Convulsions

INTERACTION WITH OTHER MEDICINAL PRODUCTS AND OTHER FORMS OF INTERACTION:
Interaction studies have only been performed in adults.

Cardiovascular effects: Haloperidol is contraindicated in combination with medicinal products known to prolong the QTc interval. Examples include:
- Class IA antiarrhythmics (e.g. disopyramide, quinidine).
- Class III antiarrhythmics (e.g. amiodarone, dofetilide, dronedarone, ibutilide, sotalol).
- Certain antidepressants (e.g. citalopram, escitalopram).

Caution is advised when haloperidol is used in combination with medicinal products known to cause electrolyte imbalance.

Medicinal products that may increase haloperidol plasma concentrations:
Examples of medicinal products that may increase haloperidol plasma concentrations include:
- CYP3A4 inhibitors – alprazolam, fluvoxamine, indinavir, itraconazole, ketoconazole, nefazodone, posaconazole, saquinavir, verapamil, voriconazole.
- CYP2D6 inhibitors – bupropion, chlorpromazine, duloxetine, paroxetine, promethazine, sertraline, venlafaxine.
- Combined CYP3A4 and CYP2D6 inhibitors: fluoxetine, ritonavir.
- Uncertain mechanism – buspirone.

Increased haloperidol plasma concentrations may result in an increased risk of adverse events, including QTc-prolongation.

Medicinal products that may decrease haloperidol plasma concentrations:
Coadministration of haloperidol with potent enzyme inducers of CYP3A4 may gradually decrease the plasma concentrations of haloperidol to such an extent that efficacy may be reduced. Examples include:
- Carbamazepine, phenobarbital, phenytoin, rifampicin, St John's Wort (Hypericum, perforatum).

Effect of haloperidol on other medicinal products: Haloperidol can increase the CNS depression produced by alcohol or CNS-depressant medicinal products, including hypnotics, sedatives or strong analgesics. An enhanced CNS effect, when combined with methyldopa, has also been reported.

Other Forms of Interaction: In rare cases the following symptoms were reported during the concomitant use of lithium and haloperidol: encephalopathy, extrapyramidal symptoms, tardive dyskinesia, neuroleptic malignant
syndrome, acute brain syndrome and coma. Most of these symptoms were reversible. Nonetheless, it is advised that in patients who are treated concomitantly with lithium and haloperidol, therapy must be stopped immediately if such symptoms occur.
Antagonism of the effect of the anticoagulant phenindione has been reported.

FERTILITY, PREGNANCY AND LACTATION:
Pregnancy: A moderate amount of data on pregnant women indicate no malformative or foetal/ neonatal toxicity of haloperidol. However, there have been isolated case reports of birth defects following foetal exposure to haloperidol, mostly in combination with other medicinal products. Animal studies have shown reproductive toxicity. As a precautionary measure, it is preferable to avoid the use of haloperidol during pregnancy.
Breast-feeding: Haloperidol is excreted in human milk. Small amounts of haloperidol have been detected in plasma and urine of breast-fed newborns of mothers treated with haloperidol.
Fertility: Haloperidol elevates prolactin level. Hyperprolactinaemia may suppress hypothalamic GnRH, resulting in reduced pituitary gonadotropin secretion. This may inhibit reproductive function by impairing gonadal steroidogenesis in both female and male patients.

UNDESIRABLE EFFECTS:
The most commonly reported adverse reactions are: extrapyramidal disorder, insomnia, agitation, hyperkinesia, headache, psychotic disorder, depression, weight increased, tremor, hypertonia, orthostatic hypotension, dystonia and somnolence.

OVERDOSE:
Symptoms and signs: The manifestations of haloperidol overdose are an exaggeration of the known pharmacological effects and adverse reactions. The most prominent symptoms are severe extrapyramidal reactions, hypotension and sedation. An extrapyramidal reaction is manifest by muscular rigidity and a generalised or localised tremor. Hypertension rather than hypotension is also possible. In extreme cases, the patient would appear comatose with respiratory depression and hypotension that could be severe enough to produce a shock-like state. The risk of ventricular arrhythmias, possibly associated with QTc prolongation, must be considered.
Management: There is no specific antidote. Treatment is supportive. Dialysis is not recommended in the treatment of overdose because it removes only very small amounts of haloperidol. For comatose patients, a patent airway must be established by use of an oropharyngeal airway or endotracheal tube. Respiratory depression may necessitate artificial respiration. It is recommended that ECG and vital signs be monitored, and that monitoring continues until the ECG is normal. Treatment of severe arrhythmias with appropriate anti-arrhythmic measures is recommended. Hypotension and circulatory collapse may be counteracted by use of intravenous fluids, plasma or concentrated albumin and vasopressor agents, such as dopamine or noradrenaline. Adrenaline must not be used because it might cause profound hypotension in the presence of haloperidol. In cases of severe extrapyramidal reactions, parenteral administration of an antiparkinson medicinal product is recommended.

Shelf Life: Refer to label and carton.

Presentation: Haloperidol Injection I.P 5mg/ml is packaged in 1 ml ampoule.

Storage : Store protected from light at a temperature between 15° C to 25° C.
Improper storage may deteriorate the product.

The injection should be discarded if any visible particles appear.
For single use only.
Discard the unused portion.

Manufactured by:

AMERICAN REMEDIES © Care & Cure with Research

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(An ISO 9001-2015 Certified Company)
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