For the use of RMP of Hospital or Laboratory only

Haloperidol Decanoate Injection

AMERICAN HPDOL DEPOT 50 Injection For I.M. Use Only

Composition:

Each ml contains :

Haloperidol Decanoate eq. to Haloperidol	BP	50mg
Benzyl Alcohol (As preservative)	IP	1.5% w/v
Oily Base		q.s.

DESCRIPTION

Haloperidol decanoate is the decanoate ester of the butyrophenone, haloperidol. It has a markedly extended duration of effect. It is available in sesame oil in sterile form for intramuscular (IM) injection. The structural formula of haloperidol decanoate, 4-(4-chlorophenyl)-1-[4-(4-fluorophenyl)-4-oxobutyl]-4 piperidinyl decanoate, is:

Haloperidol decanoate is almost insoluble in water (0.01 mg/mL), but is soluble in most organic solvents.

CLINICAL PHARMACOLOGY

Haloperidol decanoate 50 and haloperidol decanoate 100 are the long-acting forms of haloperidol, an antipsychotic. The mechanism of action of haloperidol for the treatment of schizophrenia is unclear. However, its efficacy could be mediated through its activity as an antagonist at central dopamine type 2 receptors.

Administration of haloperidol decanoate in sesame oil results in slow and sustained release of haloperidol. The plasma concentrations of haloperidol gradually rise, reaching a peak at about 6 days after the injection, and falling thereafter, with an apparent half-life of about 3 weeks. Steady state plasma concentrations are achieved within 2 to 4 months in patient receiving monthly injections. The relationship between dose of haloperidol decanoate and plasma haloperidol concentration is roughly linear for doses below 450 mg. It should be noted, however, that the pharmacokinetics of haloperidol decanoate following intramuscular injections can be quite variable between subjects.

INDICATIONS AND USAGE

Haloperidol decanoate 50 and Haloperidol decanoate 100 are indicated for the treatment of patients with schizophrenia who require prolonged parenteral antipsychotic therapy.

CONTRAINDICATIONS

Since the pharmacologic and clinical actions of haloperidol decanoate 50 and haloperidol decanoate 100 are attributed to haloperidol as the active medication, Contraindications, Warnings, and additional information are those of haloperidol, modified only to reflect the prolonged action.

Haloperidol 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

Combined Use of Haloperidol and Lithium

An encephalopathic syndrome (characterized by weakness, lethargy, fever, tremulousness and confusion, extrapyramidal symptoms, leukocytosis, elevated serum enzymes, BUN, and fasting blood sugar) followed by irreversible brain damage has occurred in a few patients treated with lithium plus haloperidol. A causal relationship between these events and the concomitant administration of lithium and haloperidol has not been established; however, patients receiving such combined therapy should be monitored closely for early evidence of neurological toxicity and treatment discontinued promptly if such signs appear.

Information for Patients

Haloperidol decanoate 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 ambulatory patient should be warned accordin
gly.

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

Usage in Pregnancy

Rats or rabbits administered oral haloperidol at doses of 0.5 to 7.5 mg/kg, which are approximately 0.2 to 7 times the maximum recommended human dose (MRHD) of 20 mg/day based on mg/m^2 body surface area. showed an increase in incidence of resorption, reduced fertility, delayed delivery and pup mortality. No fetal abnormalities were observed at these doses in rats or rabbits. Cleft palate has been observed in mice administered oral haloperidol at a dose of 0.5 mg/kg, which is approximately 0.1 times the MRHD based on mg/m^2 body surface area.

There are no adequate and well-controlled studies 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. Causal relationships were not established with these cases. Since such experience does not exclude the possibility of fetal damage due to HALOPERIDOL, haloperidol decanoate should be used during pregnancy or in women likely to become pregnant only if the benefit clearly justifies a potential risk to the fetus.

DOSAGE AND ADMINISTRATION

Haloperidol decanoate 50 and haloperidol decanoate 100 should be administered by deep intramuscular injection. A 21 gauge needle is recommended. The maximum volume per injection site should not exceed 3 ml. DO NOT ADMINISTER INTRAVENOUSLY.

Parenteral drug products should be inspected visually for particulate matter and discoloration prior to administration, whenever solution and container permit.

Haloperidol decanoate 50 and haloperidol decanoate 100 are intended for use in schizophrenic patients who require prolonged parenteral antipsychotic therapy. These patients must be previously stabilized on antipsychotic medication before considering a conversion to haloperidol decanoate. Furthermore, it is recommended that patients being considered for haloperidol decanoate therapy have been treated with, and tolerate well, short-acting haloperidol in order to reduce the possibility of an unexpected adverse sensitivity to haloperidol. Close clinical supervision is required during the initial period of dose adjustment in order to minimize the risk of overdosage or reappearance of psychotic symptoms before the next injection. During dose adjustment or episodes of exacerbation of symptoms of schizophrenia, haloperidol decanoate therapy can be supplemented with short-acting forms of haloperidol.

The dose of haloperidol decanoate 50 or haloperidol decanoate 100 should be expressed in terms of its haloperidol content. The starting dose of haloperidol decanoate should be based on the patient's age, clinical history, physical condition, and response to previous antipsychotic therapy. The preferred approach to determining the minimum effective dose is to begin with lower initial doses and to adjust the dose upward as needed. For patients previously maintained on low doses of antipsychotics (e.g. up to the equivalent of 10 mg/day oral haloperidol), it is recommended that the initial dose of haloperidol decanoate be 10-15 times the previous daily dose in oral haloperidol equivalents; limited clinical experience suggests that lower initial doses may be adequate.

Initial Therapy

Conversion from oral haloperidol to haloperidol decanoate can be achieved by using an initial dose of haloperidol decanoate that is 10 to 20 times the previous daily dose in oral haloperidol equivalents.

In patients who are elderly, debilitated, or stable on low doses of oral haloperidol (e.g. up to the equivalent of 10 mg/day oral haloperidol), a range of 10 to 15 times the previous daily dose in oral haloperidol equivalents is appropriate for initial conversion.

In patients previously maintained on higher doses of antipsychotics for whom a low dose approach risks recurrence of psychiatric decompensation and in patients whose long-term use of haloperidol has resulted in a tolerance to the drug, 20 times the previous daily dose in oral haloperidol equivalents should be considered for initial conversion, with downward titration on succeeding injections.

The initial dose of haloperidol decanoate should not exceed 100 mg regardless of previous antipsychotic dose requirements. If, therefore, conversion requires more than 100 mg of haloperidol decanoate as an initial dose, that dose should be administered in two injections, i.e. a maximum of 100 mg initially followed by the balance in 3 to 7 days.

Maintenance Therapy

The maintenance dosage of haloperidol decanoate must be individualized with titration upward or downward based on therapeutic response. The usual maintenance range is 10 to 15 times the previous daily dose in oral haloperidol equivalents dependent on the clinical response of the patient.

Non-Teratogenic Effects

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 have been reports of agitation, hypertonia, hypotonia, tremor, somnolence, respiratory distress, and feeding disorder in these neonates. These complications have varied in severity; while in some cases symptoms have been self-limited, in other cases neonates have required intensive care unit support and prolonged hospitalization.

HALOPERIDOL decanoate should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus.

Storage : Store in a cool, dry & dark place.

Protect from direct sunlight.

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