



Peridol®

Haloperidol
Antipsychotic

COMPOSITION

Peridol® tablet : Each tablet contains haloperidol BP 5 mg.

Peridol® injection : Each 2 ml contains haloperidol BP 10 mg.

PHARMACOLOGY

Peridol (Haloperidol) is a highly effective neuroleptic butyrophenone drug with a wide range of actions. Although the complex mechanism is not clearly established haloperidol is known to produce a selective effect on the central nervous system by competitive blockade of dopamine receptors and increased turnover of brain dopamine. There is some blockade of alpha-adrenergic receptors of the autonomic system.

Haloperidol is rapidly absorbed after oral administration. Distribution is rapid to extravascular tissues, especially liver and adipose tissue. It is approximately 92% bound to plasma proteins. Haloperidol crosses the blood brain barrier and is excreted in human breast milk. Haloperidol is extensively metabolized by oxidative dealkylation and ultimately conjugated with glycine. Half life is approximately 20 hours.

INDICATION

Peridol is indicated in the following cases-

Adults:

- Schizophrenia: treatment of symptoms and prevention of relapse (oral and IM)
- Other psychoses, especially paranoid (oral and IM)
- Mania and hypomania(oral and IM)
- Mental or behavioural problems such as aggression, hyperactivity and self- mutilations in the mentally retarded and in patients with organic brain damage
- As an adjunct to short-term management of moderate to severe psychomotor agitation, excitement, violent or dangerously impulsive behavior (oral and IM)
- Intractable hiccup (oral)
- Restlessness and agitation in the elderly (oral)

CNS PREPARATIONS

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- Gilles de la Tourette syndrome and severe tics (oral)
- Nausea and vomiting (IM)

Children (Oral administration only) :

- Childhood behavioral disorders especially when associated with hyperactivity and aggression
- Gilles de la Tourette syndrome
- Childhood schizophrenia

DOSAGE AND ADMINISTRATION

Dosage for all indications should be individually determined and is best initiated and titrated under close clinical supervision. To determine the initial dose consideration should be given to the patients age, severity of symptoms and previous response to other neuroleptics. The normal starting dose should be halved, followed by a gradual titration to achieve an optimal response.

Oral Administration

Adults:

Schizophrenia, Psychoses, Mania and Hypomania, Mental or behavioral problems, Psychomotor agitation, Excitement, Violent or dangerously impulsive behavior, Organic brain damage.

Initial dosage: Moderate symptomatology 1.5-3.0 mg bd or tds.

Severe symptomatology/resistant patients 3.0-5.0 mg bd or tds

The same starting doses may be employed in adolescents, who in certain cases, may require up to 30 mg or exceptionally up to 60 mg/day

In resistant schizophrenics daily dosages up to 100 mg (or rarely up to 120 mg) may be necessary to achieve an optimal response.

Maintenance dosage: Once satisfactory control of symptoms has been achieved dosage, dosage should be gradually reduced to the lowest maintenance dose, often as low as 5 mg /day. Too rapid a dosage reduction should be avoided.

Restlessness or agitation in elderly: Initial dose 1.5- 3.0 mg bd or tds titrated to attain an effective maintenance dose (1.5-5.0 mg daily)

Gilles de la tourette syndrome/Severe tics/Intractable hiccup: Starting dose

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1.5 mg tds adjusted according to response. A daily maintenance dose of 10 mg may be required in Gilles de la tourette syndrome.

For control of acutely agitated patients with moderate symptoms 2-10 mg IM. Peridol® can also be administered by IV route.

Nausea and vomiting 1-2 mg IM.

Children:

Childhood behavioural disorder/schizophrenia: Total daily maintenance dose of 0.025-0.05 mg/kg/day. Half the total dose should be given in the morning and the other half in the evening, up to a maximum of 10 mg daily. Not recommended for parenteral use in children.

CONTRAINDICATION AND PRECAUTION

Comatose states; CNS depression; Parkinson's disease; known hypersensitivity to haloperidol ; lesions of the basal ganglia.

Caution is advised in patients with liver disease, renal failure, epilepsy and conditions predisposing to epilepsy (e.g. alcohol withdrawal and brain damage) or convulsions. Haloperidol should only be used with great caution in patients with disturbed thyroid function.

SIDE EFFECT

Extrapyramidal symptoms, acute dystonia, parkinsonian rigidity, tremor, oculogyric crises and laryngeal dystonia, confusional states or epileptic fits, depression, sedation, agitation, drowsiness, insomnia, headache, vertigo and apparent exacerbation of psychotic symptoms, nausea, loss of appetite, constipation and dyspepsia, dry mouth as well as excessive salivation, blurred vision, urinary retention have been reported.

DRUG INTERACTION

Potentially hazardous interactions

Lithium: The combination of haloperidol with lithium may predispose to the neuroleptic malignant syndrome, but this should not be a problem unless very high dose of lithium is given.

Dopamine antagonists: Co-administration of antidopaminergic antiemetics increases the risk of extrapyramidal adverse effects.

Other CNS depressants: An additive depressant effect occurs.

Indomethacin: An idiosyncratic reaction of haloperidol and indomethacin to produce severe drowsiness has been reported.

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Other significant interactions: Carbamazepine and rifampicin may reduce plasma concentrations of haloperidol.

USE IN PREGNANCY AND LACTATION

There is no proven harmful effect in the first trimester, however there have been some reports of limb malformations, so the drug is best avoided if possible. The principal hazard in late pregnancy is extrapyramidal adverse effects in the neonate.

The drug is excreted only in trace amounts and sedation or extrapyramidal rigidity in the neonate can occur but is rarely a problem.

HOW SUPPLIED

Peridol® Tablet: Box containing 10 x 10 tablets in strip pack.

Peridol® Injection: Box containing 2 x 5 ampoules.



CNS PREPARATIONS