

# HADOL-5 TABLETS

## **NAME AND STRENGTH OF ACTIVE INGREDIENT(S):**

Each tablet contains:

Haloperidol.....5mg

## **PRODUCT DESCRIPTION:**

A green, round, scored of diameter 7mm flat tablet with 'MPI' marking.

## **PHARMACODYNAMICS:**

Haloperidol is known to produce a selective effect on the central nervous system by competitive blockage of postsynaptic dopamine receptors in the mesolimbic dopaminergic system and an increased turnover of brain dopamine to produce an antipsychotic action.

## **PHARMACOKINETICS:**

Haloperidol is readily absorbed from the gastro-intestinal tract. It is metabolised in the liver and is excreted in the urine and, via the bile, in the faeces; there is evidence of enterohepatic recycling. Owing to the first-pass effect of metabolism in the liver, plasma concentrations following oral administration are lower than those following intramuscular administration. Moreover, there is wide intersubject variation in plasma concentrations of haloperidol, but in practice, no simple correlation has been found between haloperidol plasma concentrations and its therapeutic effect. Haloperidol has been reported to have a plasma half-life ranging from about 13 to nearly 40 hours. Haloperidol is extensively bound (about 92%) to plasma proteins. It is widely distributed in the body and crosses the blood-brain barrier. Haloperidol is excreted in breast milk.

## **INDICATION:**

### **Psychotic disorder:**

For the management of the manifestations of acute and chronic psychotic disorders including schizophrenia, manic states, and drug-induced psychoses, such as steroid psychosis. It may also be useful in the management of aggressive and agitated patients, including patients with chronic brain syndrome or mental retardation.

### **Gilles de la Tourette's syndrome:**

Haloperidol is indicated for the control of tics and vocalisations of Tourette's syndrome in children and adults.

## **RECOMMENDED DOSAGE:**

Adults : 1.25- 2.5 mg two to three times a day initially, the dosage being gradually adjusted as needed and tolerated.

Maximum limits: 100mg daily.

Elderly/ debilitated: Initially half adult dose, the dosage being increased gradually as needed and tolerated.

## **ROUTE OF ADMINISTRATION:**

To be taken orally.

## **CONTRAINDICATIONS:**

CNS depression and Parkinson's disease.

## **WARNINGS AND PRECAUTIONS:**

Use with caution in patients with hepatic or cardiovascular disease, convulsive disorder and in geriatric patients. It should be used during pregnancy or in women likely to become pregnant only when the potential benefits justify the risk to the foetus. Haloperidol is distributed into milk. Nursing should not be undertaken in women receiving haloperidol.

## **INTERACTIONS WITH OTHER MEDICAMENTS:**

1. **CNS Depressants:** Haloperidol may potentiate the action of other CNS depressants such as opiates or other analgesics, barbiturates or other sedatives, anaesthetics, or alcohol. When haloperidol is used concomitantly with other CNS depressant, caution should be taken to avoid excessive sedation.
2. **Lithium:** An acute encephalopathic syndrome has occurred, especially when high serum lithium concentrations were present. Evidence of adverse neurologic effects should be observed for such combination and prompt discontinuation of medication if signs or symptoms appear.
3. **Anticoagulants:** Haloperidol has been reported to antagonise the anticoagulant activity of phenidione.
4. Increase in intraocular pressure occurred in patients receiving anticholinergic drugs, including antiparkinsonian agents, concurrently with haloperidol.

Dementia has reportedly occurred in patients receiving haloperidol and methyl dopa concomitantly. Patients should be carefully observed for adverse psychiatric symptoms if the drugs are used concurrently.

### **PREGNANCY AND LACTATION:**

Neonates exposed to antipsychotic drugs during the third trimester of pregnancy are at risk for extrapyramidal and/or withdrawal symptoms following delivery. There have been reports of agitation, 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 hospitalisation. Hadol-5 Tablets should be used during pregnancy only if the potential benefit justifies the potential risk to the foetus.

### **SIDE EFFECTS:**

#### **Extrapyramidal reactions:**

Occur frequently, especially during the first few days of therapy. Symptoms including parkinsonian symptoms, akathisia, tardive dystonia, and dystonic reactions.

#### **Tardive dyskinesia:**

May occur in some patients during long-term administration or it may occur following discontinuance of the drug. The risk appears to be greater in geriatric patients receiving high dosages of the drug, especially female.

#### **Other nervous system effects:**

Insomnia, restless, anxiety, euphoria, agitation, drowsiness, depression, lethargy, headache, confusion, vertigo and tonic-clonic seizures. Adverse effects include dry mouth, blurred vision, constipation and urinary retention.

#### **Hematologic effects:**

Leukopenia and leukocytosis, anaemia, and rarely agranulocytosis but only when combined with other drugs.

#### **Endocrine and Metabolic effects:**

Galactorrhoea, mastalgia, gynecomastia, increased libido, impotence, hyper/hypoglycemia, and hyponatremia occurred in some patients.

#### **Other adverse effects:**

Tachycardia, hypotension, hypertension, and ECG changes may occur. Impaired liver function and/or jaundice, maculopapular and acneform dermatologic reactions, photosensitivity, alopecia, anorexia, nausea, diarrhoea, hypersalivation, dyspepsia, vomiting, cataracts, retinopathy and visual disturbances, hyperpyrexia and heat stroke have also been reported.

### **SYMPTOMS AND TREATMENT OVERDOSE:**

#### **Symptoms:**

In general, symptoms of overdosage may be an exaggeration of adverse effects. Patients would appear comatose with respiratory depression and hypotension severe enough to produce shock-like state.

#### **Treatment:**

Treatment is essentially symptomatic and supportive with possible utilisation of the following:

- i) Inducing emesis or initiating gastric lavage, immediately followed by administration of activated charcoal.
- ii) Establishing a patent airway and mechanically assisting respiration, if necessary.
- iii) Counteracting hypotension and circulatory collapse by use of intravenous fluids, plasma or concentrated albumin, and vasopressor agents such as norepinephrine. Epinephrine should not be used since it may cause paradoxical hypotension.
- iv) Administering benztropine or diphenhydramine to manage severe extrapyramidal reactions.

### **EFFECT ON ABILITY TO DRIVE AND USE MACHINE:**

Symptoms including parkinsonian symptoms, akathisia, tardive dystonia and dystonic reactions might occurred during the first few days of therapy. Activities such as driving or operating machinery should be avoided. Drivers and machine operators should be advised that there is a risk of drowsiness with Hadol-5 tablets.

### **PRECLINICAL SAFETY DATA:**

Not applicable.

### **INSTRUCTION FOR USE:**

The dosage should be gradually adjusted as needed and tolerated. Dosage is limited to 100mg daily.

### **DOSAGE FORMS AND PACKAGING AVAILABLE:**

Tablet : Blister pack: 100 x10's

### **NAME AND ADDRESS OF MANUFACTURER / PRODUCT REGISTRATION HOLDER:**

MALAYSIAN PHARMACEUTICAL INDUSTRIES SDN BHD (101323-U)

Plot 14, Lebuhraya Kampung Jawa, 11900 Bayan Lepas,  
Pulau Pinang, Malaysia.

**DATE OF REVISION:**

12/01/18