HALPEROL®
Brand of Haloperidol, USP
Neuroleptic

DESCRIPTION:
HALPEROL®, brand of Haloperidol, is the first of the butyrophenone major tranquilizers.

PROPERTIES:
HALPEROL® is a dopamine inhibitor at the mesolimbic and nigostriatal levels. Blockade of postsynaptic dopamine receptors in the mesolimbic system of the brain probably accounts for the ability of **HALPEROL®** to ameliorate schizophrenia, while the same action in the nigrostriatal pathway may account for the unwanted parkinsonism symptoms that result from prolonged administration. In case of long term therapy it is better to associate **HALPEROL®** with benzhexol. Blockade of dopamine receptors in the tuberoinfundibular dopamine pathway releases prolactin resulting in hyperprolactinemia. Thus, the same pharmacodynamic action may have distinct psychiatric, neurologic, and endocrine consequences.

PHARMACOKINETICS:
HALPEROL® is readily absorbed from the gastro-intestinal tract. Peak plasma concentrations are obtained 3 to 6 hours after ingestion. There is wide intersubject variation in plasma concentrations of **HALPEROL®**.
HALPEROL® is extensively bound (about 92%) to plasma proteins. It is widely distributed in the body and crosses the blood-brain barrier. **HALPEROL®** is excreted in breast milk. 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. It has been reported to have a plasma half-life ranging from about 13 to nearly 40 hours.

INDICATIONS:
HALPEROL® is indicated for the management of manifestations of psychotic disorders, for tics and vocal utterances of Tourette's syndrome, and for the treatment of severe behavioral problems in children including hyperactivity.

CONTRAINDICATIONS:
HALPEROL® is contraindicated in patients with known hypersensitivity to haloperidol or with severe toxic CNS depression or comatose states and in individuals with parkinson's disease.

WARNINGS:

HALPEROL® may cause bronchopneumonia, especially in the elderly, postulated to be due to decreased sensation of thirst leading to dehydration and reduced pulmonary ventilation. If any signs of dehydration appear, institute remedial measures promptly.

PRECAUTIONS:

HALPEROL® should be used with extreme caution in children and adolescents since severe dystonic reactions have occured. Use caution while treating patients with cardiovascular disorders. **HALPEROL®** may cause transient hypotension and/or precipitate anginal pain. Severe neurotoxicity may occur in patients with thyrotoxicosis.

ADVERSE REACTIONS:

Extrapyramidal reactions, especially during the first few days of treatment, have been frequently reported. Gastrointestinal disturbances such as anorexia, constipation, diarrhea, nausea, and vomiting have also been reported. Other side effects reported include: dryness of the mouth, blurred vision, skin rash, photosensitivity, alopecia, bronchospasm, hyperpyrexia and heat stroke.

DOSAGE & ADMINISTRATION:

* Psychotic disorders:
  - Adults usual: Initially 0.5 - 2 mg, 2 to 3 times daily. For severe cases 3 - 5 mg, 2 to 3 times daily increased if necessary, up to 100 mg/day.
  - Children usual: Initially 0.5 mg/day followed, if necessary, by 0.5 mg increments every week until desired therapeutic effect is obtained.

* Non-psychotic behavioral disorders and Tourette's syndrome:
  - Children usual: 0.05 - 0.075 mg/kg/day.

N.B.: - Not recommended for children under 3 years of age.
- Dose must be gradually reduced to the lowest effective maintenance level.

DRUG INTERACTIONS:

HALPEROL® potentialize the central effects of alcohol, hypnotics, anesthesics and analgesic drugs.

Enzyme inducing drugs may lower **HALPEROL®** blood levels.

Patients receiving lithium therapy, phenindione anticoagulant and phenytoin should be carefully monitored for possible drug interactions.

AVAILABILITY:

Tablets : Packs of 50 tablets each containing Haloperidol 0.5 mg, Excipient q.s. 1 tablet.
Reg. No.:
Lebanon: 27576

Packs of 30 tablets each containing Haloperidol 2 mg, Excipient q.s. 1 tablet.
Reg. No.:
Lebanon: 27578

Packs of 30 tablets each containing Haloperidol 5 mg, Excipient q.s. 1 tablet.
Reg. No.:
Lebanon: 27579

Packs of 30 tablets each containing Haloperidol 10 mg, Excipient q.s. 1 tablet.
Reg. No.:
Lebanon: 27577