Perigen Tablet/Injection

(Haloperidol)

Presentation
Perigen Tablet: Each tablet contains Haloperidol BP 5 mg.
Perigen IM Injection: Each ampoule contains 1 ml sterile solution of Haloperidol USP 5 mg for IM injection.

Pharmacodynamic Properties
Haloperidol is a central dopamine antagonist. It also has some anticholinergic properties and is an opiate receptor antagonist and acts at peripheral dopamine receptors.

Pharmacokinetics Properties
Following IM administration of 2 mg, peak plasma concentrations were similar to after oral (ie. 10µg/ml) but are reached within 20 minutes. Haloperidol is rapidly distributed throughout the body. Haloperidol is extensively metabolised by oxidative dealkylation. Metabolites are ultimately conjugated with glycine.

Indications

Perigen is indicated in the following cases-

- Schizophrenia: treatment of symptoms and prevention of relapse.
- Other psychoses; especially paranoid.
- Mania and hypomania.
- Mental or behavioral problems such as aggression, hyperactivity and self-mutilation 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.
- Nausea and vomiting.

Dosage and Administration

Tablet :
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).

Injection :

Adults:
For control of acutely agitated patients with moderate symptoms: 2-10 mg IM. Depending on the response of the patient, subsequent doses may be given every 4-8 hours, up to a maximum of 18 mg/day. Oral treatment should succeed intramuscular administration as soon as possible. Within this context, bioavailability from the oral route is about 60% of that from the IM route and readjustment of dose may be required.

Elderly:
Elderly or debilitated patients or those with previous adverse reactions to neuroleptic agents may require less haloperidol, and half the normal starting dose may be sufficient for therapeutic purpose. In such patients, the optimum response is usually achieved with more gradual titration and at lower dose levels.

Children: Not recommended for parenteral use in children.

Nausea and vomiting: 1-2 mg IM

Contraindications
Known hypersensitivity to Haloperidol, CNS depression and basal ganglia lesions. Haloperidol should not be administered to patients in coma. Clinically significant cardiac disorders (e.g. recent acute myocardial infarction, uncompensated heart failure, arrhythmias treated with class IA and III antiarrhythmic medicinal products), QTc interval prolongation, history of ventricular arrhythmia or Torsades de pointes, Uncorrected hypokalemia, other QT prolonging drugs.

Side Effects
May cause drowsiness or blurred vision. Other side effects include stomach upset, loss of appetite, headache, dry mouth, sweating, sleep disturbances or restlessness. Immediately Notification to doctor is necessary if patient develop: chest pain, aching muscles and joints, unusual bleeding or bruising, tremors, skin rash, involuntary movements of the face/ tongue/mouth (chewing movements, puckering, twitching tongue), difficulty breathing, dizziness. Immediate notification to doctor is necessary if any of these highly unlikely but very serious side effects occur: fainting, irregular heartbeat.

Precautions
Before taking Haloperidol, patient have to inform doctor if he/she have: Parkinson's disease, liver or kidney problems, heart disease, thyroid problems, blood vessel disease, glaucoma, an enlarged prostate (difficulty urinating), allergies, asthma/ emphysema/chronic bronchitis or other lung disease, a history of seizures. Before having surgery, including dental surgery, with a general anesthetic, has to inform doctor about taking haloperidol. Patient should limit intake of alcohol as alcohol adds to the drowsiness caused by haloperidol. Haloperidol may make skin more sensitive to the sun. Patient should stay out of the sun and wear protective clothing, sunscreen and sunglasses. Exposure to extreme heat or cold should be avoided. Haloperidol reduces patient ability to regulate body temperature which could result in overheating or severe chilling. Patient should not swim in cold water. Have to inform doctor if patient are pregnant or breast-feeding before taking this medication.

Drug Interaction
Have to inform doctor about all prescription and nonprescription drugs those a patient may use, especially of: barbiturates, fluoxetine, carbamazepine, guanethidine, lithium, methyldopa, phenytoin, narcotic pain medications (e.g., codeine), sedatives, sleeping pills, muscle relaxants, antidepressants, drowsiness- causing antihistamines (e.g., diphenhydramine). Report other drugs which affect the heart rhythm (QTc prolongation), such as: dofetilide, pimozide, quinidine, sotalol, procainamide, sparfloxacin, "water pills" (diuretics such as furosemide or hydrochlorothiazide).

Use in Pregnancy and Lactation
The safety of Haloperidol in pregnancy has not been established. There is some evidence of harmful effects in some but not all animal studies. There have been a number of reports of birth defects following foetal exposure to haloperidol for which a causal role for haloperidol cannot be excluded. Haloperidol should be used during pregnancy only if the anticipated benefit outweighs the risk and the administered dose and duration of treatment should be as low and as short as possible. There have been isolated cases of extrapyramidal symptoms in breast-fed children. If the use of haloperidol is essential, the benefits of breast-feeding should be balanced against its potential risks.

Overdose
Symptoms of overdose may include agitation, very dry mouth, unusual drowsiness or deep sleep, slow or shallow breathing, rapid or irregular pulse, and muscle weakness, rigidity or tremor.

Storage Condition
Store in a cool and dry place, away from light. Keep out of the reach of the children.

Commercial Pack
Perigen Tablet: Each box contains 10 strip packs of 10 tablets.
Perigen IM Injection: Each box contains 2 blister packs of 5 ampoules of 1 ml sterile solution.

Manufactured by:
GENERAL Pharmaceuticals Ltd.
Gazipur, Bangladesh
GENERAL Pharmaceuticals Ltd. ISO 9001:2008 Certified Company