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 30 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 mentally retarded and in patients with Down's syndrome.
- 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 dose: Moderate symptomatology 1.5-3.0 mg bid or tds. In patients with acutely agitated patients, initial dose may be up to 10 mg/day. 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 be continued for at least 2 months.

Injection:
Adults:
Initial dose: 1.5-4.0 mg bid 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 schizophrenic patients. Dosages up to 100 mg (or rarely up to 150 mg) may be necessary to achieve an optimal response. Maintenance dosage: Oral. Should be given only on the advice of a physician. Oral treatment should be continued until the patient has reached a stable condition. Subsequent doses may be given every 4-8 hours, up to a maximum of 18 mg/day. Oral treatment should be continued until the patient has reached a stable condition.

Elderly:
Initial dose: 1.5-3.0 mg bid or tds at the rate of 60-80% of that from the IM route and readjustment of dose may be required.

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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, arrhythmia treated with class IA and III antiarrhythmic medicinal products), QTC interval prolongation, history of ventricular arrhythmia or Torsades de pointes, Uncontrolled 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 disturbance or restlessness. Immediately 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, arthritis, emphysema, bronchitis or other lung disease, a history of heart disease, breathing, abnormal heartbeat, heart rhythm disturbance, or a heart attack. 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, phentolamine, 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: