AGOG Pharma Ltd.
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LEAFLET

AGOHAL-5

Haloperidol Tablet BP 5 mg

Each uncoated tablet contains :-
Haloperidol BP ..... 5 mg.

Properties:
Haloperidol is a buterophenone with actions and uses similar to those of the Phenothiazines and Chlorpromazine. Haloperidol is known to produce a selective effect on the central nervous system (CNS) by competitive blockade of postsynaptic dopamine receptors in the mesolimbic dopaminergic system and an increased turnover of brain dopamine to produce an antipsychotic action. Haloperidol is readily absorbed from the gastro-intestinal tract. It is metabolized in the liver and in excreted in the urine and, via the bile, and faeces. Haloperidol has been reported to have a plasma half-life ranging from about 13 to nearly 40 hours. Haloperidol is very extensively bound to plasma proteins. It is widely distributed in the body and crosses the blood-brain barrier.

Indications:
Schizophrenia and related psychoses, particularly maina, tranquilization and emergency control in behavioural disturbances, short-term adjuctive treatment of severe anxiety, motor tics and intractable hiccup.

Dosage:
The usual dose for the treatment of psychoses is 0.5 to 5 mg twice or three times daily. In severe psychoses or resistant patients doses of up to 100mg may be required. The suggested dose in children over 3 years of age is 0.050 mg per kg body-weight daily in divided doses, increased cautiously, if necessary, up to 0.150 mg per kg daily. Haloperidol is used in the management of Gilles de la Tourrette's syndrome. A suitable dosage is reported to be up to about 10mg daily.
A suggested dose of Haloperidol for the management of behaviour disorders in disturbed and schizophrenic children is 0.050mg per kg body-weight daily (in 2 divided doses), increased cautiously, if necessary, up to 0.075mg per kg daily.

Side-effects:
Extrapyramidal symptoms (reversed by dose reduction or antimuscarinic drugs) and, on prolonged administration, occasionally tardive dyskinesia, hypothermia (occasionally pyrexial), drowsiness, apathy, pallor, nightmares, insomnia, depression, and, more rarely, agitation. Antimuscarinic symptoms such as dry mouth, nasal congestion, constipation, difficulty with micturition, and blurred vision cardiovascular symptoms such as hypotension and arrhythmias, endocrine effects such as menstrual disturbances, galactorrhoea, gynaecomastia, impotence, and weight gain, sensitivity reactions such as agranulocytosis, leucopenia, leucocytosis, and haemolytic anaemia, photosensitization, contact sensitisation, rashes and jaundice, lupus erythematosus-like syndrome have been reported. With prolonged high dosage, corneal and lens opacities and purplish pigmentation of the skin, cornea, conjunctiva, and retina.

Precautions:
Haloperidol should be administered with caution to patients with liver disease, renal failure, phaeochromocytoma, thyrotoxicosis, epilepsy or convulsions. Acute withdrawal symptoms including nausea, vomiting and insomnia have very rarely been described after abrupt cessation of high doses of antipsychotic drugs. Haloperidol may produce sedation and impairment of alertness. This response may be potentiated by alcohol.

Pregnancy:
Adequate studies in humans have not been done. However, there have been some reports of limb malformations with material use of Haloperidol along with other drugs of suspected teratogenicity during the first trimester. Also, some rodent studies have shown an increase in incidence of fetal resorption, delayed delivery, and neonatal death with doses 2 to 20 times the usual maximum human dose of Haloperidol. Cleft palate has been observed in a study with mice given 15 times the human dose of Haloperidol.

Breast-feeding:
Haloperidol is excreted in breast milk. Animal studies have shown that Haloperidol is excreted in milk in quantities sufficient to cause sedation and motor function impairment in the nursing offspring. Concurrent breast-feeding and Haloperidol therapy is not recommended.

Children:
Haloperidol is not recommended for use in children up to 3 years of age. Children are highly susceptible to the extrapyramidal side-effects, especially dystonias.

Drug Interactions:
In common with all neuroleptics, Haloperidol can increase the central nervous system depression produced by other CNS – depressasnt drugs, including alcohol, hypnotics, sedatives or strong analgesics. An enhanced CNS effect, when combined with Methyldopa, has been reported.
Haloperidol may antagonize the action of Adrenaline and other sympathomimetic agents and reverses the blood pressure lowering effects of adrenergic-blocking agents such as Guanethidine.
Haloperidol may impair the metabolism of tricyclic antidepressants (clinical significance unknown) and the antiparkinson effects of Levodopa. The dosage of anticonvulsants may need to be increased to take account of the lowered seizure threshold.
Antagonism of the effect of Phenindione has been reported.
Neurotoxic reactions during combined treatment with Lithium and Haloperidol have been reported, although there is no known mechanism for this effect. One report showing symptomless EEG abnormalities on the combination has suggested that EEG monitoring might be advisable. It is recommended that Lithium levels should always be maintained below 1mmol/l when combined with Haloperidol. If unexplained pyrexia occurs in the presence of extrapyramidal side-effects both Lithium and Haloperidol should be stopped immediately.

Contra-indications:
Haloperidol is contra-indicated in patients with comatose states, Parkinson's disease or a sensitivity to Haloperidol.

Overdosage:
Treatment of Haloperidol overdosage generally involves symptomatic and supportive care. There is no specific antidote for Haloperidol intoxication; however, anticholinergic or antiparkinsonian drugs may be useful in controlling extrapyramidal reactions associated with Haloperidol overdosage. Following acute ingestion of the drug, the stomach should be emptied by inducing emesis or by gastric lavage. If the patient is comatose, having seizures, or lacks the gag reflex, gastric lavage may be performed if an endotracheal tube with cuff inflated is in place to prevent aspiration of gastric contents. Activated charcoal should be administered after gastric lavage and/or emesis. ECG and vital signs should be monitored, particularly for signs of QT prolongation or dysrhythmias; monitoring should continue until the ECG is normal. Severe arrhythmias should be treated with appropriate antiarrhythmia measures. Appropriate therapy should be instituted if hypotension or excessive sedation occurs; Epinephrine should not be used.

Storage:
Store under normal storage condition (15°C to 30°C).
Protect from light.
Keep all medicines out of reach of children.

Presentation:
Blister pack of 10 x 10 Tablets
Jar pack of 1000 Tablets.

I165/01/01

Manufactured in India by:
AGOG PHARMA LTD.
Plot No. 33, Sector II, The Vasai Taluka Indl.
Co-op. Estate Ltd., Vasai (E), Dist. Thane. INDIA.