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EXP : Embossed

Price : Embossed

HALOPERIDOL

Scored Tablets

Category:

Antipsychotic, antidyskinetic, antiemetic.

Indications:

It is indicated in treatment of Psychotic disorders, Gilles de la Tourette's syndrome, Severe behavior problems.

It may also be useful in the management of aggressive and agitated patients. It is also effective in the *short-term* treatment of hyperactivity in children.

Pharmacology/Pharmacokinetics:

Mechanism of action/Effect:

Haloperidol is known to produce a selective effect on the CNS by competitive blockade of postsynaptic dopamine (D₂) receptors in the mesolimbic dopaminergic system and an increased turnover of brain dopamine to produce its tranquilizing effects. With subchronic therapy, depolarization blockade, or diminished firing rate of the dopamine neuron (decreased release) along with D₂ postsynaptic blockade results in the antipsychotic action.

Haloperidol absorption is orally 60%, with very high protein binding (92%).

Biotransformation is extensive Hepatic.

About 40% of a single oral dose is excreted in the urine within 5 days, 1% of which is unchanged drug and 15% of an oral dose is excreted in the feces by biliary elimination.

Pregnancy & Breast-feeding:

FDA Pregnancy Category is C. there are no adequate studies in humans.

Haloperidol is distributed into breast milk. Breast-feeding during haloperidol therapy is not recommended.

Drug interactions and/or related problems:

The following drug interactions and/or related problems have been selected on the basis of their potential clinical significance.

Alcohol or CNS depression-producing medications; Amphetamines; Anticholinergics or other medications with anticholinergic activity or Antidyskinetic agents or Antihistamines; Anticoagulants, coumarin- or indandione-derivative; Anticonvulsants, including barbiturates; Antidepressants, tricyclic or Maprotiline or Monoamine oxidase (MAO) inhibitors, including furazolidone, procarbazine, or selegiline or Trazodone; Bromocriptine; Bupropion; Diazoxide; Dopamine; Ephedrine; Epinephrine; Extrapyrimal reaction-causing medications; Fluoxetine; Guanadrel or Guanethidine; Levodopa or Pergolide; Lithium; Metaraminol; Methoxamine; Methylodopa; Phenylephrine.

Medical considerations/Contraindications:

Except under special circumstances, this medication should not be used when the following medical problem exists.

Drug-induced severe CNS depression.

Risk-benefit should be considered when the following medical problems exist:

Active Alcoholism; severe Cardiovascular disease. Epilepsy; Glaucoma or predisposition to; Hepatic function impairment; Hyperthyroidism or thyrotoxicosis; Parkinson's disease; Pulmonary insufficiency; Renal function impairment; Sensitivity to haloperidol; Urinary retention.

Side/Adverse Effects:

Children are highly susceptible to extrapyramidal effects.

Geriatric and debilitated patients are more prone to develop extrapyramidal side effects.

The following have been selected on the basis of their potential clinical significance

Those indicating need for medical attention

Incidence more frequent: Akathisia; dystonic extrapyramidal effects; tic-like or twitching movements; twisting movements of body; inability to move eyes; weakness of arms and legs; parkinsonian extrapyramidal effects difficulty in speaking or swallowing; loss of balance control; mask-like face; shuffling walk; stiffness of arms or legs; trembling and shaking of hands and fingers.

Incidence less frequent: Allergic reaction; anticholinergic effects; CNS effect; decreased thirst, or unusual tiredness or weakness; orthostatic hypotension persistent tardive dyskinesia; puffing of cheeks; rapid or worm-like movements of tongue; uncontrolled chewing movements; uncontrolled movements of the arms and legs.

Incidence rare: Agranulocytosis; heat stroke; obstructive jaundice; neuroleptic malignant syndrome (NMS) tardive dystonia.

Those indicating need for medical attention only if they continue or are bothersome

Incidence more frequent: Blurred vision; changes in menstrual period; constipation; dryness of mouth; swelling or soreness in breasts in females; unusual secretion of milk; weight gain.

Incidence less frequent: Decreased sexual ability; drowsiness; increased sensitivity of skin to sun; nausea or vomiting.

Those indicating the need for medical attention if they occur after the medication is discontinued

Withdrawal emergent dyskinesia.

Overdose:

Clinical effects of overdose: In general, symptoms of overdose may be an exaggeration of adverse effects.

Treatment of overdose: Treatment is essentially symptomatic and supportive.

Dosing:

Usual adult and adolescent dose: Antipsychotic; antidyskinetic 0.5-5 mg two or three times a day initially, the dosage being gradually adjusted as needed and tolerated.

Usual adult prescribing limits: 100 mg a day.

Usual pediatric dose: Psychotic disorders: Children 3 to 12 years of age or 15 to 40 kg of body weight: initially 0.05 mg per kg of body weight a day (in 2-3 divided doses), the daily dose being increased gradually up to a total of 0.150 mg per kg of body weight a day.

Nonpsychotic behavior disorders and Tourette's syndrome: Children 3 to 12 years of age or 15 to 40 kg of body weight: Oral, initially 0.05 mg per kg of body weight a day (in 2-3 divided doses), the daily dose being increased gradually up to a total of 0.075 mg per kg of body weight a day.

Infantile autism: Children 3 to 12 years of age or 15 to 40 kg of body weight: 0.025 mg per kg of body weight a day, up to 0.05 mg per kg of body weight a day.

Note: There is little evidence that pediatric dosages exceeding 6 mg a day produce additional improvement in behavior or in tics.

Note: Dosage regimen for children younger than 3 years of age has not been established.

Usual geriatric dose: 0.5 mg to 2 mg two or three times a day, the dosage being increased gradually as needed and tolerated.

Note: The dose for debilitated patients is the same as the geriatric dose.

How supplied:

0.5 and 5 mg haloperidol tablets. 10 blisters of 10's in a folding box with leaflet.

Storage:

Store below 30°C, protect from direct sunlight and moisture.



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