Material Safety data sheet

HALOPERIDOL TABLETS, USP

Strength: 0.5/1.0/2.0/5.0/10.0/20.0 mg. **Pack Size:** 100/1000 Tablets per bottle **Revision No.:** 00

EMERGENCY OVERVIEW

HALOPERIDOL TABLETS, USP contain Haloperidol and excipients generally considered to be non-toxic and non-hazardous in small quantities and under conditions of normal occupational exposure.

Section 1. Identification of the substance

Identification of the product

Product name:	Haloperidol Tablets USP
Formula:	$C_{21}H_{23}Cl\ F\ NO_2$
Chemical Name:	4-[4-(p-chlorophenyl)-4-hydroxy-piperidino]-4'-fluorobutyrophenone
Therapeutic Category	Major tranquilizers

Manufacturer / supplier identification

Company:	**Cadila Healthcare Ltd. Ahmedabad, India**
Contact for information:	Tel.: +91 79 6868100 Fax: +91 79 3750319
Emergency telephone No.	Tel.: +91 79 6868100

Section 2. Composition / information on ingredients

Component	Exposure Limit	CAS No.
Principle Component :		
Haloperidol, USP 0.5 mg or 1 mg or 2 mg or 5 mg or 10 mg or 20 mg.	Not Found	52-86-8
Inactive Ingredients :		
Calcium stearate,	Not Found	1592-23-0
Dibasic calcium phosphate dihydrate,	Not Found	7789-77-7
Povidone (PVP K 30),	Not Found	9003-39-8
Sodium starch glycolate	Not Found	9063-38-1
Starch.	Not Found	119-58-4
Permitted Colors	Not Found	

Section 3. Health Hazards Information

Dose and Administration

There is considerable variation from patient to patient in the amount of medication required for treatment. As with all antipsychotic drugs, dosage should be individualized according to the needs and response of each patient.

INITIAL DOSAGE RANGE

Adults

Moderate Symptomatology 0.5 mg to 2 mg b.i.d. or t.i.d.
Severe Symptomatology 3 mg to 5 mg b.i.d. or t.i.d.

Children

The following recommendations apply to children between the ages of 3 and 12 years (weight range 15 to 40 kg).
Haloperidol is not intended for children under 3 years old.

Maintenance Dosage:

Upon achieving a satisfactory therapeutic response, dosage should then be gradually reduced to the lowest effective maintenance level.

Adverse Effects

yperammonemia has been reported in a 51/2 year old child with citrullinemia, an inherited disorder of ammonia excretion, following treatment with haloperidol.

Body as a Whole:

Neuroleptic malignant syndrome (NMS), hyperpyrexia and heat stroke have been reported with haloperidol

Cardiovascular Effects:

Tachycardia, hypotension, hypertension and ECG changes

Hematologic Effects:

Reports have appeared citing the occurrence of mild and usually transient leukopenia and leukocytosis, minimal decreases in red blood cell counts, anemia, or a tendency toward lymphomonocytosis.

Liver Effects:

Impaired liver function and/or jaundice have been reported.

Dermatologic Reactions:

Maculopapular and acneiform skin reactions and isolated cases of photosensitivity and loss of hair.

Endocrine Disorders:

Lactation, breast engorgement, mastalgia, menstrual irregularities, gynecomastia, impotence,increased libido, hyperglycemia, hypoglycemia and hyponatremia.

Gastrointestinal Effects:

Anorexia, constipation, diarrhea, hypersalivation, dyspepsia, nausea and vomiting.

Autonomic Reactions:

Dry mouth, blurred vision, urinary retention, diaphoresis and priapism.

Respiratory Effects:

Laryngospasm, bronchospasm and increased depth of respiration.

Special Senses:

Cataracts, retinopathy and visual disturbances.

Over Dose Effect	In general, the symptoms of overdosage would be an exaggeration of known pharmacologic effects and adverse reactions, the most prominent of which would be: 1) severe extrapyramidal reactions, 2) hypotension, or 3) sedation. The patient would appear comatose with respiratory depression and hypotension which could be severe enough to produce a shock-like state. The extrapyramidal reaction would be manifest by muscular weakness or rigidity and a generalized or localized tremor as demonstrated by the akinetic or agitans types respectively.
Medical Conditions	Haloperidol is indicated for use in the management of manifestations of psychotic disorders. Haloperidol is indicated for the control of tics and vocal utterances of Tourette's Disorder in children and adults. Haloperidol is effective for the treatment of severe behavior problems in children of combative, explosive hyperexcitability
Contraindications	Haloperidol is contraindicated in severe toxic central nervous system depression or comatose states from any cause and in individuals who are hypersensitive to this drug or have Parkinson's disease.
Pregnancy Comments	There are no well controlled studies with haloperidol in pregnant women. There are reports, however, of cases of limb malformations observed following maternal use of haloperidol along with other drugs which have suspected teratogenic potential during the first trimester of pregnancy. Causal relationships were not established in these cases. Since such experience does not exclude the possibility of fetal damage due to haloperidol, this drug should be used during pregnancy or in women likely to become pregnant only if the benefit clearly justifies a potential risk to the fetus. Infants should not be nursed during drug treatment.
Pregnancy Category	**Not Known**

Section 4. First aid measures

General	Remove from exposure. Remove contiminated Clothing. Person devloping serious hypersensitivity reaction must receive medical attention
Overdose Treatment	Gastric lavage or induction of emesis should be carried out immediately followed by administration of activated charcoal. Since there is no specific antidote, treatment is primarily supportive. A patent airway must be established by use of an oropharyngeal airway or endotracheal tube or, in prolonged cases of coma, by tracheostomy. Respiratory depression may be counteracted by artificial respiration and mechanical respirators. Hypotension and circulatory collapse may be counteracted by use of intravenous fluids, plasma, or concentrated albumin, and vasopressor agents such as metaraminol, phenylephrine and norepinephrine.Epinephrine should not be used. In case of severe extrapyramidal reactions, antiparkinson medication should be administered. ECG and vital signs should be monitored especially for signs of Q-T prolongation or dysrhythmias and monitoring should continue until the ECG is normal. Severe arrhythmias should be treated with appropriate anti-arrhythmic measures.

Section 5. Fire – fighting measures

Flash point	Not Found	**Upper Flammable Limit:**	Not Found
Auto-Ignition Temperature:	Not Found	**Lower Flammable Limit:**	Not Found
Extinguishing Media	Water Spray, dry chemical, carbon dioxide or foam as appropriate for surrounding fire and material.	**Fire and Explosion Hazard**	This material is assumed to be combustible. As with all dry powders it is advisable to ground mechanical equipment in contact with the dry material to dissipate the potential build up of static electricity.

Fire Fighting Procedure As with all fires, evacuate personnel to a safe area. Fire fighter should use self-contained breathing equipment and protective clothing.

Section 6. Storage / Spill / Disposal Measures

Storage	Store at 20°-25°C (68°-77°F) Dispense in a tight, light-resistant container.
Spill Response	Wear approved respiratory protection, chemically compatible gloves and protective clothing. Wipe up spillage or collect spillage using high efficiency vacuum cleaner. Avoid breathing dust. Place spillage in appropriately labelled container for disposal. Wash spill site.
Disposal	Dispose the waste in accordance with all applicable Federal, State and local laws.

Section 7. Exposure controls and personal protection

Respiratory Protection	Protection from inhalation is not normally necessary. If ventilation is inadequate or dust is likely to generate, use of suitable dust mask would be appropriate.
Skin Protection	Skin protection is not normally necessary, however it is good practice to avoid contact with chemical to use suitable gloves when handling.
Eye protection	Eye protection is not normally necessary. If concerned wear protective goggles or glasses. Wash hands prior to touching eye and in particular handling contact lenses.
Protective Clothing	Protective clothing is not normally necessary, however it is good practice to use apron.

Section 8. Physical and chemical properties

Appearance	Haloperidol Tablets USP, 0.5 mg are white, capsule-shaped, flat-faced, beveled-edge tablets debossed with the logo of 'ZD 01' on one side and bisect on the other side		
Solubility in water	No Data Available	**Odour**	Odourless
Boiling point	No Data Available	**Melting Point**	No Data Available
Evaporation rate	No Data Available	**Vapour density**	No Data Available
Reactivity in water	No Data Available	**Evaporation rate**	No Data Available
Percentage Volatile by volume	No Data Available	**Specific gravity**	No Data Available
Vapour pressure	No Data Available		
Other information	Not Applicable		

Section 9. Physical Hazards

Condition to avoid	Avoid exposure to extreme heat, light and moisture.	**Stable**	Stable under normal ambient and anticipated storage and handling conditions.
Decomposition Products	No Data Available	**Hazardous Reaction**	No data available.
Incompatibilities	No data available.		

Section 10. Toxicological information

General	Handling of formulated product is not expected to cause any toxicological affects. The data pertains to the ingredient in formulations, rather than this specie formulation.
Target organ	Eye contact, Skin contact and inhalation is not great risk as this product is tablet.
other	Rodents given 2 to 20 times the usual maximum human dose of haloperidol by oral or parenteral routes showed an increase in incidence of resorption, reduced fertility, delayed delivery and pup mortality. No teratogenic effect has been reported in rats, rabbits or dogs at dosages within this range, but cleft palate has been observed in mice given 15 times the usual maximum human dose. Cleft palate in mice appears to be a nonspecific response to stress or nutritional imbalance as well as to a variety of drugs, and there is no evidence to relate this phenomenon to predictable human risk for most of these agents.

Section 11. Ecological information

No data available on Ecotoxicity

Section 12. Other information

None

Date of issue: 28/02/06 **Supersedes edition of:** New Edition

The information contained herein is based on the state of our knowledge. It Characterises the product with regard to the appropriate safety precautions. It does not represent a guarantee of the properties of the product.