ESSENTIAL

SUMMARY OF PRODUCT INFORMATION

Haldol® Decanoas

haloperidol decanoate 50 mg/ml
5 ampoules @ 1 ml

COMPOSITION
Each ml of Haldol Decanoas 50 mg/ml is expressed in terms of the haloperidol content and is equivalent to 70.52 mg haloperidol decanoate.

PHARMACEUTICAL FORM
Solution for injection.

Slightly amber, slightly viscous solution, free from visible foreign material.

PHARMACOLOGICAL PROPERTIES
Pharmacodynamic Properties
Pharmacotherapeutic group: antipsychotics, ATC Code N05AD01

Mechanism of action
Haloperidol decanoate is an ester of haloperidol and decanoic acid, and as such, a depot antipsychotic belonging to the butyrophenones group. After intramuscular injection, haloperidol decanoate is gradually released from muscle tissue and hydrolyzed slowly into free haloperidol which enters the systemic circulation.

Haloperidol is a potent central dopamine type 2 receptor antagonist, and at recommended dosages, has low alpha 1 antiadrenergic activity and no antihistaminergic or anticholinergic activity.

Pharmacodynamic effects
Haloperidol suppresses delusions and hallucinations as a direct consequence of blocking dopaminergic signaling in the mesolimbic pathway. The central dopamine blocking effect has activity on the basal ganglia (nigrostriatal bundles). Haloperidol causes effective psychomotor sedation, which explains the favourable effect on manias.

The activity on the basal ganglia probably underlies the undesirable extrapyramidal motor effects (dystonia, akathisia and parkinsonism).

The antidopaminergic effects of haloperidol on lactotropes in the anterior pituitary explain hyperprolactinemia due to inhibition of dopamine mediated tonic inhibition of prolactin secretion.

Clinical studies
In clinical studies, patients were mostly reported to have received prior treatment with orally administered haloperidol before converting to haloperidol decanoate. Occasionally, patients had previously been treated orally with another antipsychotic medicinal product.

Pharmacokinetic Properties
Absorption
Administration of haloperidol decanoate as a depot intramuscular injection results in a slow and sustained release of free haloperidol. The plasma concentrations rise gradually, usually peaking within the first week after injection.
Steady state plasma levels are reached within 2 to 4 months in patients receiving monthly injections.

Distribution

Mean haloperidol plasma protein binding in adults is approximately 88 to 92%. There is a high inter subject variability for plasma protein binding. Haloperidol is rapidly distributed to various tissues and organs, as indicated by the large volume of distribution (mean values 8 to 21 L/kg after intravenous dosing). Haloperidol crosses the blood brain barrier easily. It also crosses the placenta and is excreted in breast milk.

Metabolism
Haloperidol is extensively metabolized in the liver. The main metabolic pathways of haloperidol in humans include glucuronidation, ketone reduction, oxidative N dealkylation and formation of pyridinium metabolites. The metabolites of haloperidol are not considered to make a significant contribution to its activity. The cytochrome P450 enzymes CYP3A4 and CYP2D6 are involved in haloperidol metabolism. Inhibition or induction of CYP3A4, or inhibition of CYP2D6, may affect haloperidol metabolism. A decrease in CYP2D6 enzyme activity may result in increased haloperidol concentrations.

Excretion
The terminal elimination half-life of haloperidol after intramuscular injection with haloperidol decanoate is on average 3 weeks. This is longer than for the non-decanoate formulations, where the haloperidol terminal elimination half-life is on average 24 hours. Haloperidol apparent clearance after extravascular administration ranges from 0.9 to 1.5 L/h/kg and is reduced in poor metabolizers of CYP2D6 substrates. The inter-subject variability (coefficient of variation, %) in haloperidol clearance was estimated to be 44% in a population pharmacokinetic analysis in patients with schizophrenia. After intravenous haloperidol administration, 21% of the dose was eliminated in the feces and 33% in the urine. Less than 3% of the dose is excreted unchanged in the urine.

Linearity/non-linearity
The pharmacokinetics of haloperidol following intramuscular injections of haloperidol decanoate are dose related. The relationship between dose and plasma haloperidol level is approximately linear for doses below 450 mg.

Special populations
Elderly
Haloperidol plasma concentrations in elderly patients were higher than in younger adults administered the same dosage. Results from small clinical studies suggest a lower clearance and a longer elimination half-life of haloperidol in elderly patients. The results are within the observed variability in haloperidol pharmacokinetics. Dosage adjustment is recommended in elderly patients (see *POSOLOGY AND METHOD OF ADMINISTRATION – Special populations: Elderly*).

Renal impairment
The influence of renal impairment on the pharmacokinetics of haloperidol has not been evaluated. Since less than 3% of administered haloperidol is eliminated unchanged in the urine, impairment of renal function is not expected to affect its elimination. Therefore, dosage adjustment is not required in patients with renal impairment, but caution is advised when treating patients with renal impairment.
Because of the high haloperidol distribution volume and its high protein binding, only very small amounts are removed by dialysis.

Hepatic impairment
The influence of hepatic impairment on the pharmacokinetics of haloperidol has not been evaluated. However, hepatic impairment may have significant effects on the pharmacokinetics of haloperidol because it is extensively metabolized in the liver. Therefore, dosage adjustment and caution is advised in patients with hepatic impairment (see *POSOLOGY AND METHOD OF ADMINISTRATION – Special populations: Hepatic impairment and SPECIAL WARNINGS AND SPECIAL PRECAUTIONS FOR USE– Hepatobiliary concerns*).

Pharmacokinetic/pharmacodynamics relationships
Therapeutic concentrations

Based on clinical studies with haloperidol, therapeutic response is obtained in most patients with acute or chronic schizophrenia at plasma concentrations of 1 to 10 ng/mL, while some patients may require concentrations up to 17 ng/mL.

In patients with first episode schizophrenia treated with short acting haloperidol formulations, therapeutic response may be obtained at concentrations as low as 0.6 to 3.2 ng/mL, as estimated based on measurements of D2 receptor occupancy and assuming that a D2 receptor occupancy level of 60 to 80% is most appropriate for obtaining therapeutic response and limiting extrapyramidal symptoms.
Due to the high inter subject variability in haloperidol pharmacokinetics and the concentration effect relationship, it is recommended to adjust the individual haloperidol decanoate dose based on the patient's response. This must take into account the time after a change in dose to achieve a new steady state plasma concentration and the additional time to elicit a therapeutic response.

Cardiovascular effects
The risk of QTc interval prolongation increases with haloperidol dose and with haloperidol plasma concentrations.

Preclinical Safety Data
Nonclinical data reveal no special hazards for humans based on conventional studies of local tolerability, repeat dose toxicity, genotoxicity and carcinogenicity. In rodents, haloperidol administration showed a decrease in fertility, limited teratogenicity as well as embryo-toxic effects.

Haloperidol has been shown to block the cardiac hERG channel in several published studies *in vitro*. In a number of *in vivo* studies intravenous administration of haloperidol in some animal models has caused significant QTc interval prolongation, at doses around 0.3 mg/kg i.v., giving C_{max} plasma levels 4 to 8 times higher than the maximum therapeutic plasma concentration of17 ng/mL in clinical studies. These intravenous doses which prolonged QTc did not cause arrhythmias. In some animal studies higher intravenous haloperidol doses of 1 mg/kg or greater caused QTc prolongation and/or ventricular arrhythmias at C_{max} plasma levels 22 to 81 times higher than the maximum therapeutic plasma concentration in clinical studies.

CLINICAL PARTICULARS
Therapeutic indications
Haldol Decanoas is indicated for the maintenance treatment of schizophrenia and other chronic psychoses in adults.

POSOLOGY AND METHOD OF ADMINISTRATION
Patients must be previously stabilized on oral haloperidol before converting to Haldol Decanoas.

Haldol Decanoas is for intramuscular use only and must not be administered intravenously (see *Instructions for use/handling*).

Haldol Decanoas is administered as a deep intramuscular injection in the gluteal region. It is recommended to alternate between the two gluteal muscles for subsequent injections. As the administration of volumes greater than 3 ml is uncomfortable for the patient, such large injection volumes are not recommended.

Treatment initiation and dose titration must be carried out under close clinical supervision.

The individual dose will depend on both the severity of the symptoms and the current oral haloperidol dose. Patients must always be maintained on the lowest effective dose.

Dosage - Adults
Table 1. Haloperidol decanoate dose recommendations for adults aged 18 years and above

Transition from oral haloperidol • A haloperidol decanoate dose of 10 to 15 times the previous daily dose of oral haloperidol is recommended. • Based on this conversion, the haloperidol decanoate dose will be 25 to150 mg for most patients, • The maximum recommended initial haloperidol decanoate dose is 100 mg.
Continuation of treatment • Adjust the haloperidol decanoate dose by up to 50 mg every 4 weeks (based on individual patient response) until an optimal therapeutic effect is obtained. • The most effective dose is expected to range between 50 and 200 mg. • The maximum dosage is 300 mg every 4 weeks.
Dosing interval • Usually 4 weeks between injections. • Adjust the dosing interval as required (based on individual patient response).
Supplementation with non-decanoate haloperidol • Consider supplementation with non-decanoate haloperidol during transition to Haldol Decanoas, dose adjustment or episodes of exacerbation of psychotic symptoms (based on individual patient response). • The combined total dose of haloperidol from both formulations must not exceed the corresponding maximum oral haloperidol dosage of 20 mg/day.

Special populations

Pediatrics

The safety and efficacy of Haldol Decanoas in children and adolescents below 18 years of age have not been established. No data are available.

Elderly

Table 2. Haloperidol decanoate dose recommendations for elderly patients

Transition from oral haloperidol • A low haloperidol decanoate dose of 12.5 to 25 mg is recommended.
Continuation of treatment • Adjust the haloperidol decanoate dose by up to 25 mg every 4 weeks (based on individual patient response) until an optimal therapeutic effect is obtained. • The maximum dosage is half that specified for adults.
Dosing interval • Usually 4 weeks between injections. • Adjust the dosing interval as required (based on individual patient response).

Supplementation with non-decanoate haloperidol

- Consider supplementation with non-decanoate haloperidol during transition to Haldol Decanoas, dose adjustment or episodes of exacerbation of psychotic symptoms (based on individual patient response).
- The combined total dose of haloperidol from both formulations must not exceed the corresponding maximum oral haloperidol dosage of 10 mg/day or the previously administered oral haloperidol dose in patients who have received long-term treatment with oral haloperidol.

Renal impairment

The influence of renal impairment on the pharmacokinetics of haloperidol has not been evaluated. Caution is advised when treating patients with renal impairment (see *Pharmacokinetic Properties – Special populations: Renal impairment*).

Hepatic impairment

The influence of hepatic impairment on the pharmacokinetics of haloperidol has not been evaluated. Since haloperidol is extensively metabolized in the liver, it is recommended to halve the initial dose, and adjust the dosage with smaller increments and at longer intervals than in patients without hepatic impairment (*see SPECIAL WARNINGS AND SPECIAL PRECAUTIONS FOR USE – Hepatobiliary concerns* and *Pharmacokinetic Properties – Special populations: Hepatic impairment*).

Maintenance therapy

The maintenance dosage of haloperidol decanoate must be individualized with titration upward or downward based on therapeutic response. The usual maintenance range is 10 to 15 times the previous daily dose in oral haloperidol equivalents dependent on the clinical response of the patients.

SPECIAL WARNINGS AND SPECIAL PRECAUTIONS FOR USE

Since haloperidol is metabolized in the liver, caution is advised in patients with liver diseases.

Mortality

Rare cases of sudden death have been reported in psychiatric patients receiving antipsychotic drugs, including Haldol Decanoas (see *Adverse Reactions*).

Elderly patients with dementia-related psychosis treated with antipsychotic drugs are at an increased risk of death. Analyses of seventeen placebo-controlled trials (modal duration of 10 weeks), largely in patients taking atypical antipsychotic drugs, revealed a risk of death in drug-treated patients of between 1.6 to 1.7 times the risk of death in placebo-treated patients. Over the course of a typical 10-week controlled trial, the rate of death in drug-treated patients was about 4.5%, compared to a rate of about 2.6% in the placebo group. Although the causes of death were varied, most of the deaths appeared to be either cardiovascular (e.g., heart failure, sudden death) or infectious (e.g., pneumonia) in nature. Observational studies suggest that, similar to atypical antipsychotic drugs, treatment with conventional antipsychotic drugs may increase mortality. The extent to which the findings of increased mortality in observational studies may be attributed to the antipsychotic drug as opposed to some characteristic(s) of the patients has not yet been elucidated.

Cardiovascular effects

Very rare reports of QTc interval prolongation and/or ventricular arrhythmias, in addition to rare reports of sudden death, have been reported with haloperidol (see *Adverse Reactions*). They may occur more frequently with high doses, in predisposed patients, or with a QTc interval that exceeds 500 ms.

As QTc interval prolongation has been observed during haloperidole treatment, caution is advised in patients with QTc-prolonging conditions (long QT-syndrome, hypokalaemia, hypomagnesemia, electrolyte imbalance, drugs known to prolong QTc, cardiovascular diseases, family history of QTc prolongation), especially if

haloperidol is given parenterally (see *INTERACTIONS WITH OTHER MEDICINAL PRODUCTS AND OTHER FORMS OF INTERACTION– Cardiovascular effects*).
The risk of QTc prolongation and/or ventricular arrhythmias may be increased with higher doses or with parenteral use, particularly intravenous administration.

Haloperidol decanoate must not be administered intravenously.

Tachycardia and hypotension (including orthostatic hypotension) have also been reported in occasional patients (see *Adverse Reactions*).

Cerebrovascular events
In randomized, placebo-controlled clinical trials in the dementia population, there was an approximately 3-fold increased risk of cerebrovascular adverse events with some atypical antipsychotics. Observational studies comparing the stroke rate in elderly patients exposed to any antipsychotic to the stroke rate in those not exposed to such medicinal products reported an increased stroke rate among exposed patients. This increase may be higher with all butyrophenones, including haloperidol. The mechanism for this increased risk is not known. An increased risk cannot be excluded for other patient populations. Haldol Decanoas must be used with caution in patients with risk factors for stroke.

Neuroleptic malignant syndrome
In common with other antipsychotic drugs, Haldol Decanoas has been associated with neuroleptic malignant syndrome: a rare idiosyncratic response characterized by hyperthermia, generalized muscle rigidity, autonomic instability, altered consciousness, and increased serum creatine phosphokinase levels. Hyperthermia is often an early sign of this syndrome. Antipsychotic treatment should be withdrawn immediately and appropriate supportive therapy and careful monitoring instituted.

Tardive dyskinesia
As with all antipsychotic drugs, tardive dyskinesia may appear in some patients on long-term therapy or after drug discontinuation. The syndrome is mainly characterized by rhythmic involuntary movements of the tongue, face, mouth or jaw. The manifestations may be permanent in some patients. The syndrome may be masked when treatment is reinstituted, when the dosage is increased or when a switch is made to a different antipsychotic drug. Treatment should be discontinued as sson as possible.

Extrapyramidal symptoms
In common with all antipsychotic drugs, extrapyramidal symptoms may occur (e.g. tremor, rigidity, hypersalivation, bradykinesia, akathisia, acute dystonia).

Antiparkinson drugs of the anticholinergic type may be prescribed as required, but should not be prescribed routinely as a preventive measure. If concomitant antiparkinson medication is required, it may have to be continued after stopping Haldol Decanoas if its excretion is faster than that of haloperidol to avoid the development or aggravation of extrapyramidal symptoms. The possible increase in intraocular pressure must be considered when anticholinergic drugs, including antiparkinson agents, are administered concomitantly with Haldol Decanoas.

Seizures/convulsions
It has been reported that seizures can be triggered by Haldol Decanoas. Caution is advised in patients suffering from epilepsy and in conditions predisposing to convulsions (e.g., alcohol withdrawal and brain damage).

Hepatobiliary concerns
As haloperidol is extensively metabolized by the liver, dosage adjustment and caution is advised in patients with hepatic impairment (see *POSOLOGY AND METHOD OF ADMINISTRATION – Special populations: Hepatic impairment and Pharmacokinetic Properties – Special populations: Hepatic impairment*). Isolated cases of liver function abnormalities or hepatitis, most often cholestatic, have been reported (see *Adverse Reactions*).

Endocrine system concerns

Thyroxin may facilitate haloperidol toxicity. Antipsychotic therapy in patients with hyperthyroidism should be used only with caution and must always be accompanied by therapy to achieve a euthyroid state.

Hormonal effects of antipsychotic drugs include hyperprolactinaemia, which may cause galactorrhoea, gynaecomastia and oligomenorrhea or amenorrhoea. Very rare cases of hypoglycaemia and of syndrome of inappropriate antidiuretic hormone secretion have been reported (see *Adverse Reactions*).

Venous thromboembolism
Cases of venous thromboembolism (VTE) have been reported with antipsychotic drugs. Since patients treated with antipsychotics often present with acquired risk factors for VTE, all possible risk factors for VTE should be identified before and during treatment with Haldol Decanoas and preventive measures undertaken.

Treatment initiation
Patients being considered for Haldol Decanoas therapy must be initially treated with oral haloperidol to exclude the possibility of an unexpected adverse sensitivity to haloperidol.

Patients with depression
As with all antipsychotic drugs, Haldol Decanoas should not be used alone where depression is predominant. It may be combined with antidepressants to treat those conditions in which depression and psychosis coexist (see *INTERACTIONS WITH OTHER MEDICINAL PRODUCTS AND OTHER FORMS OF INTERACTION*).

Adverse Reactions
Throughout this section, adverse reactions are presented. Adverse reactions are adverse events that were considered to be reasonably associated with the use of haloperidol decanoate (or non-decanoate formulations) based on the comprehensive assessment of the available adverse event information. A causal relationship with haloperidol decanoate (or non-decanoate formulations) cannot be reliably established in individual cases. Further, because clinical trials are conducted under widely varying conditions, adverse reaction rates observed in the clinical trials of a drug cannot be directly compared to rates in the clinical trials of another drug and may not reflect the rates observed in clinical practice.

Clinical trial data
Comparator and open-label trial data – adverse drug reactions reported at ≥ 1% incidence
The safety of Haldol Decanoas (15-500 mg/month) was evaluated in 410 subjects who participated in 13 clinical trials in the treatment of schizophrenia or a schizoaffective disorder.

Adverse Reactions reported by ≥ 1% of Haldol Decanoas-treated subjects in these trials are shown in Table 3.

Table 3. Adverse Reactions Reported by ≥ 1% of Haldol Decanoas-treated Subjects in Comparator and Open-Label Clinical Trials of Haldol Decanoas

System/Organ Class Adverse Reaction	**Haloperidol decanoate** (n=410) %
Nervous System Disorders	
Extrapyramidal disorder	13.6
Tremor	8.0
Parkinsonism	7.3
Somnolence	4.9
Masked facies	4.1
Akathisia	3.4
Sedation	2.7
Gastrointestinal Disorders	
Dry mouth	3.4
Constipation	2.0
Salivary hypersecretion	1.2

Musculoskeletal and Connective Tissue Disorders	
Muscle rigidity	6.1
Reproductive System and Breast Disorders	
Sexual dysfunction	1.5
General Disorders and Administration Site Conditions	
Injection site reaction	1.2
Investigations	
Weight increased	2.9

Comparator and open-label trial data – adverse drug reactions reported at <1% incidence
Additional adverse reactions that occurred in <1% of Haldol Decanoas-treated subjects either of the above trial data are listed below in Table 4.

Table 4. Adverse Reactions Reported by <1 % of Haldol Decanoas-treated Subjects in Comparator and Open-Label Clinical Trials of Haldol Decanoas

Nervous System Disorders
Akinesia
Dyskinesia
Hypertonia
Dystonia
Cogwheel rigidity
Eye Disorders
Vision blurred
Visual disturbance
Oculogyric crisis
Cardiac Disorders
Tachycardia

Adverse reactions identified in clinical trials with haloperidol (non-decanoate formulations)
Adverse reactions relating to the active moiety that were identified in clinical trials with haloperidol (non-decanoate formulations) are listed in Table 5:

Table 5: Adverse reactions identified in clinical trials with haloperidol (non-decanoate formulations)

Endocrine Disorders:
Hyperprolactinaemia

Psychiatric Disorders:
Libido decreased; Loss of libido; Restlessness

Nervous System Disorders:
Neuroleptic malignant syndrome; Tardive dyskinesia; Bradykinesia; Dizziness; Hyperkinesia; Hypokinesia; Motor dysfunction; Muscle contractions involuntary; Nystagmus

Vascular Disorders:
Hypotension; Orthostatic hypotension

Musculoskeletal and Connective Tissue Disorders:
Trismus; Torticollis; Muscle spasms; Musculoskeletal stiffness; Muscle twitching

Reproductive System and Breast Disorders:
Amenorrhoea; Galactorrhoea; Menstrual disorder; Erectile dysfunction; Breast discomfort; Breast pain; Dysmenorrhoea; Menorrhagia

General Disorders and Administration Site Conditions:
Gait disturbance

Postmarketing Data

Adverse events first identified as adverse reactions during postmarketing experience with haloperidol are included in Tables 6. The postmarketing review was based on review of all cases including haloperidol and haloperidol decanoate-containing products. In the table, the frequencies are provided according to the following convention:

Very common	≥ 1/10
Common	≥ 1/100 to < 1/10
Uncommon	≥ 1/1,000 to < 1/100
Rare	≥ 1/10,000 to < 1/1,000
Very rare	< 1/10,000, including isolated reports

In Table 6, adverse reactions are presented by frequency category based on spontaneous reporting rates., when known.

Table 6: Adverse Reactions Identified During Postmarketing Experience with Haloperidol (oral, solution, or decanoate) by Frequency Category Estimated from Spontaneous Reporting Rates

Blood and Lymphatic System Disorders	
Very rare	Agranulocytosis, Pancytopenia, Thrombocytopenia, Leukopenia, Neutropenia
Immune System Disorders	
Very rare	Anaphylactic reaction, Hypersensitivity
Endocrine Disorders	
Very rare	Inappropriate antidiuretic hormone secretion
Metabolic and Nutritional Disorders	
Very rare	Hypoglycemia
Psychiatric Disorders	
Very rare	Psychotic disorder, Agitation, Confusional state, Depression, Insomnia
Nervous System Disorders	
Very rare	Convulsion, Headache
Cardiac Disorders	
Very rare	Torsade de pointes, Ventricular fibrillation, Ventricular tachycardia, Extrasystoles
Respiratory, Thoracic and Mediastinal Disorders	
Very rare	Bronchospasm, Laryngospasm, Laryngeal edema, Dyspnoea
Gastrointestinal Disorders	
Very rare	Vomiting, Nausea
Hepatobiliary Disorders	
Very rare	Acute hepatic failure, Hepatitis, Cholestasis, Jaundice, Liver function test abnormal
Skin and Subcutaneous Tissue Disorders	
Very rare	Angioedema, Leukocytoclastic vasculitis, Dermatitis exfoliative, Urticaria, Photosensitivity reaction, Rash, Pruritus, Hyperhidrosis
Musculoskeletal and Connective Tissue Disorders	
Very rare	Rhabdomyolisis

Renal and Urinary Disorders
Very rare Urinary retention

Pregnancy, Puerperium and Perinatal Conditions
Very rare *Drug withdrawal syndrome neonatal*

Reproductive System and Breast Disorders
Very rare Priapism, Gynaecomastia

General Disorders and Administration Site Conditions
Very rare Sudden death, Face oedema, Edema, Hypothermia, Hyperthermia, Injection site abscess

Investigations
Very rare Electrocardiogram QT prolonged, Weight decreased

CONTRAINDICATIONS
Known hypersensitivity to haloperidol or to any of the excipients;
Comatose state;
Central Nervous System (CNS) depression due to alcohol or other depressant drug;
Parkinson's disease;
Dementia with Lewy bodies;
Progressive supranuclear palsy;

INTERACTIONS WITH OTHER MEDICINAL PRODUCTS AND OTHER FORMS OF INTERACTION
Cardiovascular effects
As with other antipsychotic drugs, caution is advised when Haldol Decanoas is used in combination with medications known to prolong the QTc interval (see *SPECIAL WARNINGS AND SPECIAL PRECAUTIONS FOR USE– Cardiovascular effects*). Examples include:

- Class IA antiarrhythmics (e.g. disopyramide, quinidine).
- Class III antiarrhythmics (e.g. amiodarone, dofetilide, dronedarone, ibutilide, sotalol).
- Certain antidepressants (e.g. citalopram, escitalopram).
- Certain antibiotics (e.g. erythromycin, levofloxacin, moxifloxacin).
- Certain antifungals (e.g. pentamidine).
- Certain antimalarials (e.g. halofantrine).
- Certain gastrointestinal drugs (e.g. dolasetron).
- Certain drugs used in cancer (e.g. toremifene, vandetanib).
- Certain other drugs (e.g. bepridil, methadone).

This list is not exhaustive.

It is recommended that concomitant use of other antipsychotic drugs be avoided.
Caution is advised when Haldol Decanoas is used in combination with drugs known to cause electrolyte imbalance (see *SPECIAL WARNINGS AND SPECIAL PRECAUTIONS FOR USE– Cardiovascular effects*).

Drugs that may increase haloperidol plasma concentrations
Haloperidol is metabolized by several routes (see *Pharmacokinetic Properties – Metabolism*). The major pathways are glucuronidation and ketone reduction. The cytochrome P450 enzyme system is also involved, particularly CYP3A4 and, to a lesser extent, CYP2D6. Inhibition of these routes of metabolism by another drug or a decrease in CYP 2D6 enzyme activity may result in increased haloperidol concentrations. The effect of CYP3A4 inhibition and of decreased CYP2D6 enzyme activity may be additive (see *Pharmacokinetic Properties*

– *Metabolism*). Based on limited and sometimes conflicting information, the average increase in haloperidol plasma concentrations when a CYP3A4 and/or CYP2D6 inhibitor was coadministered generally ranged between 20 and 40%, although in some cases, average increases of up to 100% have been reported. Examples of drugs that may increase haloperidol plasma concentrations (based on clinical experience or drug interaction mechanism) include:

- CYP3A4 inhibitors – alprazolam; itraconazole, ketoconazole, and some other azoles; nefazodone; certain antivirals.
- CYP2D6 inhibitors – chlorpromazine; promethazine; quinidine; paroxetine, sertraline, venlafaxine, and some other antidepressants.
- Combined CYP3A4 and CYP2D6 inhibitors – fluoxetine, fluvoxamine; ritonavir.
- Uncertain mechanism – buspirone.

This list is not exhaustive.

Increased haloperidol plasma concentrations may result in an increased risk of adverse events, including QTc interval prolongation (see *SPECIAL WARNINGS AND SPECIAL PRECAUTIONS FOR USE– Cardiovascular effects*). Increases in QTc have been observed when haloperidol was given with a combination of the metabolic inhibitors ketoconazole (400 mg/day) and paroxetine (20 mg/day).

It is recommended that patients who take haloperidol concomitantly with such medicinal products be monitored for signs or symptoms of increased or prolonged pharmacologic effects of haloperidol, and the Haldol Decanoas dose be decreased as deemed necessary.
Sodium valproate, a drug known to inhibit glucuronidation, does not affect haloperidol plasma concentrations.

Drugs that may decrease haloperidol plasma concentrations
Coadministration of haloperidol with potent enzyme inducers of CYP3A4 may gradually decrease the plasma concentrations of haloperidol to such an extent that efficacy may be reduced. Examples (based on clinical experience or drug interaction mechanism) include:

- Carbamazepine, phenobarbital, phenytoin, rifampicin, St John's Wort (Hypericum, perforatum).

This list is not exhaustive.

Enzyme induction may be observed after a few days of treatment. Maximal enzyme induction is generally seen in about 2 weeks and may then be sustained for the same period of time after the cessation of therapy with the medicinal product. Therefore, during combination treatment with inducers of CYP3A4, it is recommended that patients be monitored and the **H**aldol Decanoas dose increased or the dosage interval adjusted, as deemed necessary. After withdrawal of the CYP3A4 inducer, the concentration of haloperidol may gradually increase and therefore it may be necessary to reduce the dose of Haldol Decanoas, or adjust the dosage interval.

Effect of other drugs on haloperidol
In common with all antipsychotics drugs, haloperidol can increase the CNS depression produced by other CNS-depressant drugs, including alcohol, hypnotics, sedatives or analgesics. An enhanced CNS effect, when combined with methyldopa, has been reported.

Haloperidol may antagonize the action of adrenaline and other sympathomimetic agents and reverse the blood-pressure-lowering effects of adrenergic-blocking agents such as guanethidine.

Haloperidol may impair the antiparkinson effects of levodopa and other dopamine agonist drugs.

Haloperidol is an inhibitor of CYP 2D6. it inhibits the metabolism of tricyclic antidepressants, thereby increasing plasma levels of these drugs.

Other forms of interaction
In rare cases the following symptoms were reported during the concomitant use of lithium and haloperidol decanoate: encephalopathy, extrapyramidal symptoms, tardive dyskinesia, neuroleptic malignant syndrome, brain stem disorder, acute brain syndrome and coma. Most of these symptoms were reversible.

Nonetheless, it is advised that in patients, who are treated concomitantly with lithium and Haldol Decanoas, therapy must be stopped immediately if such symptoms occur.

Antagonism of the anticoagulant effect of phenindione has been reported.

Pregnancy and Lactation
Pregnancy
Neonates exposed to antipsychotic drugs (including haloperidol) during the third trimester of pregnancy are at risk for extrapyramidal and/or withdrawal symptoms that may vary in severity following delivery. These symptoms in neonates may include agitation, hypertonia, hypotonia, tremor, somnolence, respiratory distress, or feeding disorder. These complications have varied in severity; while in some cases symptoms have been self-limited; in other cases neonates have required additional medical treatment or monitoring.

Haldol Decanoas has shown no significant increase in fetal anomalies in large population studies. There have been isolated case reports of birth defects following fetal exposure to Haldol Decanoas in combination with other drugs. Animal studies have demonstrated a teratogenic effect of haloperidol (see section Preclinical Safety Data). Haldol Decanoas should be used during pregnancy only if the anticipated benefit justifies the potential risk to the fetus.

Breast-feeding
Haloperidol is excreted in breast milk. Small amounts of haloperidol have been detected in plasma and urine of breast-fed newborns of mothers treated with haloperidol. If the use of Haldol Decanoas is considered essential, the benefits of breast-feeding should be balanced against its potential risks.

Effects on Ability to Drive and Use Machines
Some degree of sedation or impairment of alertness may occur, particularly with higher doses and at the start of treatment and may be potentiated by alcohol. Patients should be advised not to drive or operate machinery during treatment, until their susceptibility is known.

Overdose
While overdosage is less likely to occur with parenteral than with oral medication, information pertaining to oral haloperidol is presented, modified only to reflect the extended duration of action of Haldol Decanoas.

Symptoms and signs
The manifestations of haloperidol overdose are an exaggeration of the known pharmacological effects and adverse reactions. The most prominent symptoms are: severe extrapyramidal reactions, hypotension, and sedation. An extrapyramidal reaction is manifest by muscular rigidity and a generalized or localized tremor. Hypertension rather than hypotension is also possible. In extreme cases, the patient would appear comatose with respiratory depression and hypotension that could be severe enough to produce a shock-like state. The risk of ventricular arrhythmias, possibly associated with QTc interval prolongation, should be considered.

Treatment
There is no specific antidote. Treatment is supportive. Dialysis is not recommended in the treatment of overdose because it removes only very small amounts of haloperidol (see *Pharmacokinetic Properties – Special populations: Renal impairment*).

For comatose patients, a patent airway should be established by use of an oropharyngeal airway or endotracheal tube. Respiratory depression may necessitate artificial respiration.

ECG and vital signs should be monitored and monitoring should continue until the ECG is normal. Severe arrhythmias should be treated with appropriate anti-arrhythmic measures.

Hypotension and circulatory collapse may be counteracted by use of intravenous fluids, plasma, or concentrated albumin, and vasopressor agents such as dopamine or noradrenaline (norepinephrine).

Adrenaline (epinephrine) must not be used because it might cause profound hypotension in the presence of haloperidol.

In case of severe extrapyramidal reactions, antiparkinson medication should be administered and continued for several weeks. Antiparkinson medication must be withdrawn very cautiously as extrapyramidal symptoms may emerge.

PHARMACEUTICAL PARTICULARS
List of Excipients
Benzyl alcohol, sesame oil refined.

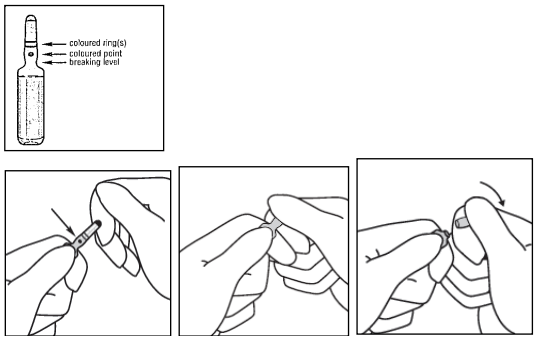
Incompatibilities
Due to the oily base, this injectable solution may not be used in infusions.

Shelf Life
3 years

Special Precautions for Storage
Store below 30°C.
Protect from light.
Keep out of reach of children.

Instructions for use/handling
Before use, roll the ampoule between the palms of the hands for a moment to warm it up.

1. Hold the ampule between the thumb and index finger, leaving the tip of the ampoule free.
2. With the other hand, hold the tip of ampule putting the index finger against the neck of ampule, and the thumb on the colored point parallel to the identification colored ring(s).
3. Keeping the thumb on the point, sharply break the tip of ampoule while holding firmly the other part of the ampule in the hand.



HOW SUPPLIED
Haldol Decanoas 50 mg/ml
Box @ 5 ampule @ 1 ml
Reg.No.: DKI1955203143A1

HARUS DENGAN RESEP DOKTER

Manufactured by Janssen Pharmaceutica NV, Beerse, Belgium
Imported and distributed by PT Soho Industri Pharmasi
Jl. Pulogadung No. 6, Kawasan Industri Pulogadung, Jakarta 13920, Indonesia – phone (021) 460-5550

For adverse event and product quality complaint, please contact pv.soho@sohoglobalhealth.com or (021) 460-5550

Based on CCDS Mar 2018_rev_KOMNAS_22Dec21

ESSENTIAL

INFORMASI PRODUK UNTUK PASIEN

HALDOL® DECANOAS
haloperidol decanoate 50 mg/ml
Larutan untuk injeksi

Baca semua informasi produk ini secara seksama sebelum Anda mulai menggunakan obat ini karena mengandung informasi penting untuk Anda.
- Simpan informasi produk ini. Anda mungkin perlu untuk membacanya lagi.
- Jika Anda memiliki pertanyaan lebih lanjut, tanyakan kepada dokter, apoteker, atau perawat Anda
- Obat ini hanya diresepkan hanya untuk Anda. Jangan memberikan obat ini kepada orang lain. Hal ini dapat membahayakan mereka, bahkan jika tanda-tanda penyakit mereka sama dengan Anda.
- Jika Anda mengalami efek samping, bicarakan dengan dokter, apoteker, atau perawat Anda. Termasuk efek samping yang tidak disebutkan dalam informasi produk ini. Lihat bagian 4.

Apa yang ada dalam informasi produk ini

1. Apakah HALDOL DECANOAS dan digunakan untuk apa

Nama obat Anda adalah HALDOL DECANOAS.

HALDOL DECANOAS mengandung zat aktif haloperidol (sebagai *haloperidol decanoate*). Obat ini termasuk dalam kelompok obat yang disebut 'antipsikotik'.

HALDOL DECANOAS digunakan pada orang dewasa yang sebelumnya telah diobati dengan haloperidol yang diberikan dengan cara diminum. Obat ini digunakan untuk penyakit yang mempengaruhi cara Anda berpikir, merasa, atau berperilaku. Semua ini termasuk masalah Kesehatan mental (seperti skizofrenia).

Penyakit ini dapat membuat Anda:
- Merasa bingung (delirium)
- Melihat, mendengar, merasakan atau mencium hal-hal yang tidak ada (halusinasi)
- Mempercayai hal-hal yang tidak benar (delusi)
- Merasa sangat curiga (paranoia)
- Merasa sangat bersemangat, gelisah, antusias, impulsif atau hiperaktif
- Merasa sangat agresif, bermusuhan atau kasar

2. Apa saja yang perlu Anda ketahui sebelum Anda diberikan HALDOL DECANOAS

Jangan gunakan HALDOL DECANOAS jika:
- Anda alergi terhadap haloperidol atau bahan lain dari obat ini (tercantum dalam bagian 6).
- Reaksi Anda menjadi sangat lambat, atau Anda merasa sangat bingung, pusing, atau mengantuk setelah minum alkohol atau setelah minum obat lain
- Anda menderita Parkinson
- Anda memiliki jenis demensia yang disebut 'Demensia *Lewy body*'
- Anda menderita kelumpuhan *supranuclear* progresif (PSP).

DISETUJUI OLEH BPOM: 02/10/2024 ID: EREG100061VR12400078

Jangan gunakan obat ini jika salah satu hal di atas terjadi pada Anda. Jika Anda tidak yakin, bicarakan dengan dokter, apoteker, atau perawat Anda sebelum diberikan HALDOL DECANOAS.

Peringatan dan pencegahan
Efek samping yang serius
HALDOL DECANOAS dapat menyebabkan masalah dengan jantung, masalah dalam mengendalikan gerakan tubuh atau anggota badan dan efek samping yang serius yang disebut 'sindrom neuroleptik maligna'. Obat ini juga dapat menyebabkan reaksi alergi yang parah dan pembekuan darah. Anda harus menyadari efek samping yang serius saat Anda menggunakan HALDOL DECANOAS karena Anda mungkin membutuhkan pengobatan dengan segera. Lihat Bagian 4 untuk mengetahui efek samping dari HALDOL DECANOAS.

Pasien dengan usia lanjut dan orang dengan demensia
Sedikit peningkatan kematian dan stroke telah dilaporkan untuk orang lanjut usia dengan demensia yang menggunakan obat antipsikotik. Bicaralah dengan dokter atau apoteker Anda sebelum menggunakan HALDOL DECANOAS jika Anda berusia lanjut, terutama jika Anda menderita demensia.

Bicaralah dengan dokter atau apoteker Anda jika Anda memiliki:
- Penyakit jantung, masalah jantung, atau siapa pun di keluarga dekat Anda memiliki riwayat meninggal mendadak karena masalah jantung
- Anda atau siapa pun dalam keluarga dekat Anda memiliki kondisi jantung yang disebut 'QT interval panjang', atau masalah lain dengan irama jantung Anda yang ditunjukkan dengan hasil pemeriksaan pada EKG (elektrokardiogram) yang abnormal
- Tekanan darah rendah, atau merasa pusing saat duduk atau berdiri
- Kadar kalium atau magnesium (atau 'elektrolit' lainnya) yang rendah dalam darah Anda
- Pernah mengalami perdarahan di otak, atau dokter Anda memberi tahu Anda bahwa Anda lebih mungkin terkena stroke daripada orang lain
- Epilepsi atau pernah mengalami konvulsi (*fits* atau kejang)
- Masalah dengan ginjal, hati, atau kelenjar tiroid Anda
- Riwayat pembekuan darah, atau orang lain dalam keluarga Anda memiliki riwayat pembekuan darah
- Depresi.

Anda mungkin perlu diawasi lebih ketat, dan jumlah HALDOL DECANOAS yang diberikan mungkin harus diubah.

Jika Anda tidak yakin apakah salah satu hal di atas berlaku untuk Anda, bicarakan dengan dokter, apoteker, atau perawat Anda sebelum Anda diberikan HALDOL DECANOAS.

Pemeriksaan kesehatan
Dokter Anda mungkin ingin melakukan pemeriksaan elektrokardiogram (EKG) untuk mengukur aktivitas listrik jantung Anda.

Anak-anak dan remaja
HALDOL DECANOAS tidak boleh digunakan pada anak-anak dan remaja di bawah usia 18 tahun. Hal ini karena obat ini belum diuji pada kelompok usia ini.

Obat-obatan lain dan HALDOL DECANOAS
Beri tahu dokter, apoteker, atau perawat Anda jika Anda sedang mengonsumsi, baru saja mengonsumsi atau mungkin sedang mengonsumsi obat-obatan lain.

Beritahu dokter Anda jika Anda sedang mengonsumsi obat antipsikotik lain. Anda tidak boleh menggunakan HALDOL DECANOAS dengan obat antipsikotik lain kecuali dokter Anda memberi tahu Anda untuk melakukannya.

Pemantauan khusus mungkin diperlukan jika Anda menggunakan litium dan HALDOL DECANOAS secara bersamaan. Beritahu dokter Anda segera dan berhenti minum kedua obat jika Anda mengalami:
- Demam yang tidak dapat Anda jelaskan atau gerakan yang tidak dapat Anda kendalikan
- Bingung, disorientasi, sakit kepala, masalah keseimbangan dan merasa mengantuk.

Ini adalah gejala-gejala dari suatu kondisi yang serius.

Obat-obatan tertentu dapat meningkatkan kemungkinan timbulnya masalah pada jantung
Beri tahu dokter Anda jika Anda mengonsumsi obat-obatan untuk:
- Masalah dengan detak jantung Anda (seperti amiodarone, dofetilide, disopyramide, dronedarone, ibutilide, quinidine dan sotalol)
- Depresi (seperti citalopram dan escitalopram)
- Infeksi bakteri (seperti eritromisin, levofloksasin, dan moksifloksasin)
- Infeksi jamur (seperti pentamidin)
- Malaria (seperti halofantrine)
- Mual dan muntah (seperti dolasetron)
- Kanker (seperti toremifene dan vandetanib)
- Menurunkan tekanan darah, seperti tablet air (diuretik).

Juga beri tahu dokter Anda jika Anda menggunakan bepridil (untuk nyeri dada atau untuk menurunkan tekanan darah) atau metadon (pereda nyeri atau untuk mengobati kecanduan narkoba).

Obat-obatan tertentu dapat mempengaruhi cara kerja HALDOL DECANOAS
Beri tahu dokter Anda jika Anda sedang mengonsumsi:
- Alprazolam atau buspirone (untuk kecemasan)
- Fluoxetine, fluvoxamine, nefazodone, paroxetine, sertraline, St John's Wort (Hypericum, perforatum) atau venlafaxine (atau obat lain untuk depresi)
- Karbamazepin, fenobarbital, atau fenitoin (untuk epilepsi)
- Rifampisin (untuk infeksi bakteri)
- Itrakonazol (atau obat lain untuk infeksi jamur)
- Tablet ketoconazole (untuk mengobati sindrom Cushing)
- Ritonavir (untuk *human immunodeficiency virus* atau HIV), atau obat antivirus lainnya
- Klorpromazin atau prometazin (untuk mual dan muntah).

Dokter Anda mungkin harus mengubah dosis HALDOL DECANOAS Anda jika Anda sedang mengonsumsi obat-obatan ini.

HALDOL DECANOAS dapat memengaruhi cara kerja obat lain
Beri tahu dokter Anda jika Anda sedang mengonsumsi obat-obatan untuk:
- Menenangkan Anda atau membantu Anda tidur (obat penenang)
- Nyeri (pereda nyeri yang kuat)
- Depresi ('antidepresan trisiklik')
- Menurunkan tekanan darah (seperti guanethidine dan methyldopa)
- Reaksi alergi berat (adrenalin)
- Penyakit Parkinson (seperti levodopa)
- Mengencerkan darah (fenindione).

Bicaralah dengan dokter Anda sebelum menggunakan atau diberi HALDOL DECANOAS jika Anda sedang mengonsumsi obat-obatan ini.

HALDOL DECANOAS dan alkohol
Meminum alkohol saat Anda menggunakan HALDOL DECANOAS mungkin membuat Anda merasa mengantuk dan kurang waspada. Ini berarti Anda harus berhati-hati dengan berapa banyak alkohol yang Anda minum. Bicaralah dengan dokter Anda mengenai meminum alkohol saat menggunakan HALDOL DECANOAS.

Kehamilan dan menyusui
Kehamilan – jika Anda sedang hamil, berpikir Anda mungkin hamil atau berencana untuk memiliki bayi, mintalah saran dari dokter Anda. Dokter Anda mungkin menyarankan Anda untuk tidak menggunakan HALDOL DECANOAS saat Anda hamil.

Masalah berikut dapat terjadi pada bayi baru lahir dari ibu yang menggunakan HALDOL DECANOAS dalam 3 bulan terakhir kehamilannya (trimester terakhir):
- Otot gemetar, otot kaku atau lemah
- Mengantuk atau gelisah
- Masalah pernapasan atau makan.

Jika Anda menggunakan HALDOL DECANOAS saat hamil dan bayi Anda mengalami salah satu dari efek samping ini, beri tahu dokter Anda.

Menyusui – bicarakan dengan dokter Anda jika Anda sedang menyusui atau berencana untuk menyusui. Ini karena sejumlah kecil obat dapat masuk ke dalam ASI dan ke bayi. Dokter Anda akan mendiskusikan risiko dan manfaat menyusui saat Anda menggunakan HALDOL DECANOAS.

Mengemudi dan menggunakan mesin
Efek samping yang terjadi dengan HALDOL DECANOAS, seperti merasa mengantuk, dapat mempengaruhi kewaspadaan Anda, terutama ketika Anda pertama kali mulai menggunakannya, atau setelah pemberian dosis tinggi. Jangan mengemudi atau menggunakan alat atau mesin apa pun tanpa membicarakan hal ini dengan dokter Anda terlebih dahulu.

3. Bagaimana cara menggunakan HALDOL DECANOAS

Dokter atau perawat Anda akan menyuntikkan HALDOL DECANOAS ke dalam otot. Satu suntikan biasanya akan bertahan selama 4 minggu.

Berapa banyak obat yang akan Anda berikan?
Dokter Anda akan memutuskan berapa banyak dosis HALDOL DECANOAS yang Anda butuhkan dan untuk berapa lama. Dokter Anda akan menyesuaikan dosis yang sesuai dengan Anda, dan mungkin juga memberi Anda jenis haloperidol yang diminum melalui mulut. Dosis HALDOL DECANOAS Anda akan bergantung pada:

- Usia Anda
- Apakah Anda memiliki masalah dengan hati Anda
- Bagaimana Anda bereaksi terhadap haloperidol di masa lalu
- Obat-obatan lain yang sedang Anda konsumsi.

Dewasa

- Dosis awal Anda biasanya antara 25 mg dan 100 mg.
- Dokter Anda mungkin menyesuaikan dosis hingga 50 mg setiap 4 minggu untuk menemukan dosis yang paling sesuai untuk Anda (biasanya antara 50 mg dan 200 mg setiap 4 minggu).
- Anda tidak akan diberikan lebih dari 300 mg setiap 4 minggu.

Usia lanjut

- Anda biasanya akan mulai dengan dosis yang lebih rendah, biasanya 12,5 mg sampai 25 mg setiap 4 minggu.
- Dokter Anda mungkin menyesuaikan dosis hingga 50 mg setiap 4 minggu untuk menemukan dosis yang paling sesuai untuk Anda.
- Anda tidak akan diberikan lebih dari 150 mg setiap 4 minggu.

Jika Anda mendapatkan terlalu banyak dosis HALDOL DECANOAS
Seorang dokter atau perawat akan memberikan obat ini kepada Anda, jadi kecil kemungkinan Anda akan diberikan terlalu banyak. Jika Anda khawatir, beri tahu dokter atau perawat.

Jika Anda melewatkan satu dosis atau berhenti menggunakan HALDOL DECANOAS
Anda tidak boleh menghentikan obat ini kecuali diinstruksikan untuk melakukannya oleh dokter Anda karena gejala Anda mungkin dapat timbul kembali. Jika Anda melewatkan janji temu, hubungi dokter Anda segera untuk membuat janji yang baru.

Jika Anda memiliki pertanyaan lebih lanjut tentang penggunaan obat ini, tanyakan kepada dokter, apoteker, atau perawat Anda.

4. Efek samping yang mungkin terjadi

Seperti semua obat lainnya, obat ini dapat menyebabkan efek samping, meskipun tidak semua orang mengalaminya.

- Masalah mengendalikan gerakan tubuh atau anggota badan (gangguan ekstrapiramidal)
- Tremor otot
- Gerakan lambat, dengan gemetar, kaku dan berjalan terseok-seok
- Mengantuk
- Kurangnya ekspresi wajah normal yang terkadang terlihat seperti topeng
- Merasa gelisah atau kesulitan duduk diam
- Mengantuk
- Mulut kering
- Sembelit
- Air liur meningkat
- Kekakuan otot
- Masalah berhubungan seks
- Iritasi atau rasa sakit di mana suntikan diberikan
- Penambahan berat badan
- Tidak bisa bergerak
- Gerakan menyentak atau memutar yang tidak dapat Anda kendalikan
- Ketegangan otot yang tidak normal
- Gerakan memutar yang tidak bisa Anda kendalikan
- Kekakuan otot dan gerakan anggota tubuh yang tidak normal
- Penglihatan kabur
- Masalah dengan penglihatan
- Gerakan mata ke atas yang tidak bisa Anda kendalikan
- Detak jantung cepat
- Tingginya kadar hormon 'prolaktin' dalam darah
- Gairah seks menurun
- Kehilangan gairah seks
- Merasa gelisah
- Reaksi serius yang menyebabkan demam tinggi, kekakuan otot yang parah, kebingungan dan kehilangan kesadaran (sindrom neuroleptik maligna)
- Gerakan mulut, lidah, rahang, dan terkadang anggota badan, yang tidak dapat Anda kendalikan
- Pergerakan lambat
- Merasa pusing
- Gerakan tubuh meningkat
- Gerakan tubuh lambat atau berkurang
- Masalah untuk menghasilkan atau mengontrol gerakan
- Kontraksi otot yang tidak bisa Anda kendalikan
- Gerakan mata cepat yang tidak bisa Anda kendalikan
- Tekanan darah rendah
- Merasa pusing saat duduk atau berdiri
- Kesulitan atau tidak bisa membuka mulut
- Kejang di leher yang tidak bisa Anda kendalikan, menyebabkan kepala berputar ke satu sisi
- Kejang otot
- Kekakuan otot dan sendi
- Kedutan otot
- Tidak ada periode menstruasi
- Produksi ASI yang tidak terduga
- Perubahan siklus menstruasi (haid)
- Kesulitan mendapatkan dan mempertahankan ereksi (impotensi)
- Ketidaknyamanan pada payudara
- Nyeri pada payudara
- Periode menstruasi yang menyakitkan
- Periode menstruasi yang panjang atau volume darah haid lebih banyak dari biasanya
- Masalah berjalan
- Penurunan drastis jumlah sel darah putih
- Jumlah semua jenis sel darah rendah
- Rendahnya jumlah 'trombosit' (sel yang membantu darah untuk membeku)
- Rendahnya jumlah sel darah putih

- Rendahnya jumlah satu jenis sel darah putih (neutrofil)
- Reaksi alergi parah yang mungkin termasuk:

- wajah, bibir, mulut, lidah, atau tenggorokan bengkak
- kesulitan menelan atau bernafas
- ruam gatal (*hives* / biduran)

- Reaksi alergi
- Tingkat tinggi 'hormon antidiuretik' dalam darah (sindrom sekresi hormon antidiuretik yang tidak tepat)
- Rendahnya kadar gula dalam darah
- Masalah kesehatan mental yang serius, seperti mempercayai hal-hal yang tidak benar (delusi) atau melihat, merasakan, mendengar atau mencium hal-hal yang tidak ada (halusinasi)
- Merasa gelisah
- Merasa bingung
- Depresi
- Sulit tidur
- Kejang
- Sakit kepala
- Irama jantung yang tidak normal, yang dapat menyebabkan hilangnya kesadaran
- Irama jantung yang tidak normal, yang menghentikan kerja jantung secara normal
- Detak jantung yang sangat cepat
- Detak jantung ekstra
- Penyempitan saluran udara di paru-paru, menyebabkan kesulitan bernapas
- Kejang singkat pada pita suara yang menyebabkan kesulitan berbicara atau bernapas
- Pembengkakan di sekitar kotak suara yang dapat menyebabkan kesulitan bernapas
- Sesak nafas
- Muntah
- Mual
- Kegagalan hati yang tiba-tiba
- Peradangan pada hati
- Penurunan aliran empedu di saluran empedu
- Masalah hati yang menyebabkan kulit atau mata menguning (*jaundice*)
- Tes darah menunjukkan fungsi hati yang abnormal
- Reaksi alergi parah yang menyebabkan wajah, bibir, mulut, lidah atau tenggorokan bengkak, yang dapat menyebabkan kesulitan menelan atau bernafas
- Peradangan pembuluh darah kecil, yang menyebabkan ruam kulit dengan benjolan kecil berwarna merah atau ungu
- Kulit mengelupas atau mengelupas
- Biduran (*hives*)
- Meningkatkan sensitivitas kulit terhadap sinar matahari
- Ruam kulit
- Gatal
- Keringat berlebihan
- Kerusakan jaringan otot (rhabdomyolysis)
- Tidak dapat buang air kecil atau mengosongkan kandung kemih sepenuhnya
- Mengidam obat pada bayi baru lahir yang ibunya minum obat saat hamil
- Ereksi penis yang persisten dan menyakitkan
- Pembesaran payudara pada pria
- Kematian mendadak
- Wajah bengkak
- Pembengkakan yang disebabkan oleh penumpukan cairan di dalam tubuh
- Suhu tubuh rendah
- Suhu tubuh tinggi
- Kumpulan nanah (abses) pada tempat suntikan diberikan
- Hasil pemeriksaan jantung abnormal pada EKG (elektrokardiogram)
- Penurunan berat badan

Jika Anda merasakan efek samping, beritahu dokter, apoteker atau perawat Anda. Hal ini termasuk kemungkinan efek samping yang tidak tercantum dalam brosur ini.

5. Bagaimana cara menyimpan HALDOL DECANOAS

Jauhkan obat ini dari pandangan dan jangkauan anak-anak.

Jangan menggunakan obat ini setelah tanggal kedaluwarsa yang tertera pada label atau dus. Tanggal kedaluwarsa mengacu pada hari terakhir bulan itu.

Jangan membuang obat-obatan melalui air limbah atau limbah rumah tangga. Tanyakan apoteker Anda bagaimana membuang obat-obatan yang tidak lagi Anda gunakan. Langkah-langkah ini akan membantu melindungi lingkungan.

6. Isi kemasan dan informasi lainnya

Apa saja kandungan HALDOL DECANOAS?
Zat aktifnya adalah haloperidol.

Tiap ml larutan 50 mg/ml mengandung 50 mg haloperidol (sebagai 70.52 mg haloperidol decanoate).

Bahan lainnya adalah benzil alcohol dan minyak wijen halus.

Seperti apa HALDOL DECANOAS dan isi kemasan
HALDOL DECANOAS adalah cairan yang sedikit kental, berwarna agak kuning, tanpa partikel yang terlihat.

HALDOL DECANOAS tersedia dalam ampul.

Haldol Decanoas 50 mg/ml
Dus @ 5 ampul @ 1 ml
No. Reg.: DKI1955203143A1

HARUS DENGAN RESEP DOKTER

Diproduksi oleh:
Janssen Pharmaceutica NV, Beerse, Belgium

Diimpor oleh:
PT Soho Industri Pharmasi
Jl. Pulogadung No. 6, Kawasan Industri Pulogadung, Jakarta 13920, Indonesia – phone (021) 460-5550

Untuk pelaporan efek samping dan keluhan kualitas produk, dapat menghubungi pv.soho@sohoglobalhealth.com atau (021) 460-5550

Based on CPPI Ver.012 2March2018