

HALDOL® DECANOATE

Haloperidol decanoate solution for injection (IM OILY INJECTION)

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about Haldol injection. It does not contain all the available information. It does not take the place of talking to your doctor or pharmacist.

All medicines have risks and benefits. Your doctor has weighed the risks of treating you with Haldol against the benefits this medicine is expected to have for you.

If you have any concerns about being treated with Haldol, ask your doctor or pharmacist.

Keep this leaflet with your medicine. You may need to read it again.

What Haldol is used for

Haldol contains the active substance haloperidol (as haloperidol decanoate). This belongs to a group of medicines called 'antipsychotics'.

Haldol is a long-acting antipsychotic. It works by correcting the chemical imbalances in the brain, which may cause mental illness.

Haldol is used in adults whose condition has previously been treated with haloperidol taken by mouth. It is used for illnesses affecting the way you think, feel or behave. These include mental health problems (such as schizophrenia).

These illnesses may make you:

- Feel confused (delirium)

- See, hear, feel or smell things that are not there (hallucinations)
- Believe things that are not true (delusions)
- Feel unusually suspicious (paranoia)
- Feel very excited, agitated, enthusiastic, impulsive or hyperactive
- Feel very aggressive, hostile or violent.

Your doctor may have prescribed Haldol for another use.

Ask your doctor or healthcare professional if you have any questions about why this medicine has been prescribed for you.

Haldol is not addictive.

Before you are given Haldol

When you must not be given it:

Do not give Haldol to anyone who is unconscious or in a coma.

You must not be given Haldol if you:

- have severe drowsiness and slowness due to illness or the use of alcohol or medicine
- feel unusually confused, dizzy or sleepy
- suffer from severe depression
- have or have ever had muscle stiffness, restricted or uncontrollable movement due to certain medical conditions, such as Parkinson's disease

- have a type of dementia called 'Lewy body dementia'
- have progressive supranuclear palsy (PSP).
- have an allergy to Haldol or any of the ingredients. See Product Description at the end of this leaflet for a list of ingredients.

Signs of allergy may include skin rash, itching, shortness of breath, and/or swollen face that may lead to difficulty breathing or swallowing.

If you think you are having an allergic reaction, tell your doctor immediately or go to the Accident and Emergency department at the nearest hospital.

Do not give Haldol if the packaging is torn or shows signs of tampering and if it is beyond the expiry date (month and year) printed on the pack.

Before you are given it:

You must tell your doctor if you:

- are pregnant or planning to become pregnant.

Like most antipsychotic medicines, Haldol is not recommended for use during pregnancy. Discuss with your doctor the risks and benefits involved in using it.

- are breast feeding or wish to breastfeed.

Small amounts of the medicine may pass into the mother's milk and on to the baby. Discuss with your doctor the risks and benefits involved in using it.

- suffer from loss of contact with reality and inability to think and judge clearly, or from a general decline mental ability (e.g. dementia related psychosis)
- have ever had bleeding in the brain, or your doctor has told you that you are more likely than other people to have a stroke
- have or have ever had a heart problem or a family history of heart problems, such as an unusual heart beat or a fast heartbeat, or are taking a heart medication
- have or have ever had low blood pressure
- have or have ever had a rare heart disorder known as QT-prolongation which sometimes runs in families
- have or have ever had uncontrolled movements of the tongue, mouth, cheeks or jaws which may progress to the arms and legs (also known as tardive dyskinesia)
- have or have ever had a sudden increase in body temperature, extremely high blood pressure and severe convulsions (also known as neuroleptic malignant syndrome)
- have or have ever had epileptic fits or convulsions (seizures)
- have depression
- have or have ever had kidney or liver disease
- have a very active thyroid gland (hyperthyroidism)
- have had blood clots, or a family history of blood clots. Blood clots in the lungs and legs have been seen in patients taking antipsychotic medicines
- experience a significant increase in weight while taking other antipsychotic medications. Clinically significant weight gain has also been reported in patients using this medicine.

Tell your doctor if:

- you are taking medicines or have medical conditions which may cause an imbalance of potassium levels in your blood
- you suffer from an imbalance of electrolytes (naturally occurring chemicals present in body fluids, that are needed for normal body functions).

If you have not told your doctor or pharmacist about any of the above, tell them before you are given Haldol.

Your doctor will advise you on whether you should receive Haldol or whether to adjust the dose or alter your treatment.

Taking other medicines:

Tell your doctor or pharmacist if you are taking any other medicines, including medicines you can buy without a prescription from a pharmacy, supermarket or health food shop.

In particular, tell your doctor or pharmacist if you are taking any of the following:

- medicines used to control depression or mood swings (such as nefazodone, buspirone, venlafaxine, fluvoxamine, fluoxetine, paroxetine, sertraline, lithium, alprazolam, chlorpromazine, citalopram, escitalopram, St John's Wort (*Hypericum perforatum*) and 'tricyclic antidepressants')
- antipsychotic medicines, used to treat mental illness
- medicines for nausea and vomiting (such as promethazine, chlorpromazine, dolasetron)
- antiviral medicines (such as ritonavir for HIV)
- antifungal medication (such as ketoconazole, itraconazole and pentamidine)
- medicines known to cause electrolyte imbalance or imbalance of naturally occurring

chemicals present in body fluids, that are needed for normal body functions.

- alcohol or medicines which make you feel drowsy or slow your reactions, such as sleeping tablets, tranquillisers or strong painkillers
- medicines used to lower high blood pressure and heart conditions (such as methyldopa, bepridil, water tablets)
- medicines used to treat fast or irregular heartbeats (arrhythmia) such as quinidine, amiodarone, dofetilide, disopyramide, dronedarone, ibutilide, sotalol
- Certain cough and cold preparations and weight reduction medicines containing substances such as adrenaline (epinephrine)
- medicines that prevent adrenaline (epinephrine) working, such as guanethidine
- antibiotics such as rifampicin, erythromycin, levofloxacin, moxifloxacin
- medicines used to prevent travel sickness, treat Parkinson's Disease or relieve stomach cramps or spasms (anticholinergics)
- medicines used to treat Parkinson's disease, such as levodopa (Levodopa)
- medicines used to treat epilepsy (such as carbamazepine, phenobarbital (phenobarbitone))
- medicines used to slow or prevent blood clotting (anticoagulants, blood thinners such as phenindione).
- methadone (a pain killer or to treat drug addiction).
- medicines used for malaria (such as halofantrine)
- medicines used for cancer (such as toremifene and vandetanib)

These medicines may be affected by Haldol or may affect how well Haldol works. Your doctor or pharmacist can tell you what to do if

you are taking any of these medicines.

Lithium

Special monitoring may be needed if you are using lithium and Haldol at the same time.

Tell your doctor straightaway and stop using both medicines if you get:

- fever you can't explain or movements you can't control
- Confused, disoriented
- a headache
- balance problems
- sleepiness

These are signs of a serious condition.

Effects on driving and operating machinery

Haldol can affect your alertness and ability to drive and operate machinery, particularly when you first start using it, or after a high dose.

Do not drive or operate any tools or machinery until your doctor says it is safe.

Do not drink alcohol.

Haldol can increase the effects of alcohol, and might make you feel sleepy and less alert. This means you should be careful how much alcohol you drink

Using Haldol

How it is given:

Haldol will be given as an injection by your doctor or nurse into a muscle in the buttocks.

Haldol should not be given into a vein.

It is usually given every four weeks, however your doctor may lengthen or shorten this time.

Your doctor will decide how much Haldol you will be given. This will

depend on your physical conditions such as your age, body weight, your medical history and conditions.

Your doctor will monitor you closely when you start receiving Haldol injection. Your dose and how often the injection is given may be altered, until the medicine controls your symptoms. Follow your doctor's instructions.

If you are elderly or physically unwell, you may need less Haldol. Your doctor may adjust your dose if necessary.

Haldol should not be used in children and adolescents under 18 years of age. This is because it has not been studied in this age group.

If you do not understand the instructions provided with this medicine, ask your doctor or pharmacist for help.

If you forget to use it:

If you have missed your next injection, contact your doctor as soon as possible and make a new appointment.

You should not stop this medicine unless told to do so as your symptoms may return.

If you are given too much (overdose):

Immediately telephone your doctor or the Poisons Information Centre for advice, or go to Accident and Emergency at your nearest hospital.

You may need urgent medical attention.

Poisons Information Centre telephone numbers:

Australia: 13 11 26

New Zealand: 0800 POISON or 0800 764 766

Keep these telephone numbers handy

As this medicine will be given to you by your doctor or nurse, it is unlikely that you will be given too much. If you are worried, tell the doctor or nurse.

Signs of overdose of Haldol may include severe tremor, fainting or drowsiness.

While you are given Haldol

Things you must do:

- Always follow your doctor's instructions carefully.
- Be sure to keep all of your doctor's appointments so that your progress can be checked. For example, your doctor may want to take an electrocardiogram (ECG) to measure the electrical activity of your heart. Seek your doctor's advice before changing or stopping Haldol treatment.
- If you are about to start taking a new medicine, tell your doctor and pharmacist that you are being given Haldol.

Tell your doctor if you become pregnant while using Haldol.

The following problems may occur in newborn babies of mothers that use Haldol in the last 3 months of their pregnancy (the last trimester):

- Muscle tremors, stiff or weak muscles
- Being sleepy or agitated
- Problems breathing or feeding.
- Medicine craving (withdrawal)

Things you must not do:

- Do not use Haldol to treat any other complaint unless your doctor says so
- Do not give this medicine to anyone else, even if their symptoms seem similar to yours.

Side Effects

All medicines can have side effects. Sometimes they are serious, most of

the time they are not. You may need medical treatment if you get some side effects. Do not be alarmed by this list of possible side effects. You may not experience any of them.

Ask your doctor or pharmacist to answer any questions you may have.

Tell your doctor if you experience any of the following:

- drowsiness or sleepiness
- restlessness or difficulty sitting still
- difficulty sleeping
- constipation
- dry mouth
- increased salivation
- nausea or vomiting
- low body temperature
- problems with skin such as flaking or peeling of skin, itching, rash, hives, sensitivity to sunlight
- excessive sweating
- changes in sex drive in both men and women, problems having sex
- difficulty getting and keeping an erection (impotence), painful and persistent erection
- enlarged breasts in men
- problems with menstrual period such as having no periods, painful period, long and heavy periods or changes in menstrual cycles
- unexpected production of breast milk
- breast pain, discomfort
- weight gain or weight loss
- muscle stiffness or weakness, abnormal muscle tension, joint stiffness
- breakdown of muscle tissue (rhabdomyolysis)
- lack of normal facial expressions that sometimes looks like a mask
- redness, burning or pain at the site Haldol is given including collection of pus at the site
- vision problems such as blurred vision
- low blood pressure which may cause dizziness or headache
- low blood cell counts such as white blood cells, platelets
- abnormal hormone levels in blood such as prolactin, antidiuretic hormone
- being unable to pass urine or empty the bladder completely
- swelling caused by fluid build-up in the body
- low level of sugar in the blood
- problems with liver such as jaundice, abnormal blood tests of the liver, liver failure
- shaking or tremors
- difficulty speaking
- uncontrollable twitching or jerking movements of the arms and legs; worm-like movements of the tongue or other uncontrolled movements of the mouth, tongue, cheeks or jaws which may progress to the arms and legs
- being unable to move, difficulty opening the mouth
- uncontrollable muscle spasms affecting the eyes, head, neck and body
- feeling agitated, confused or depressed
- Serious mental health problem, such as believing things that are not true (delusions) or seeing, feeling, hearing or smelling things that are not there (hallucinations)
- disease of the brain affecting movement, resulting in trembling, rigid posture, slow movements and a shuffling, unbalanced walk (parkinsonism)

Tell your doctor immediately if you notice any of the following as you may need urgent medical care:

- difficulty in breathing, or deeper and faster breathing.
- allergic reactions with signs such as skin rash, itching, shortness of breath, and/or swelling of the

face, lips or throat that may lead to difficulty breathing or swallowing.

- a sudden increase in body temperature, extremely high blood pressure, stiff muscles, decreased mental alertness or fits (seizures).
- abnormal heart rhythm (in ECG), fast or unusual heartbeat.

Other side effects not listed above may also occur in some people. Tell your doctor if you notice any other effects.

After using Haldol

Storage

Keep Haldol Injection in the pack until it is time to use them.

Keep Haldol Injection in a cool dry place where the temperature is below 25°C. Protect it from light.

Keep your medicines where children cannot reach them. A locked cupboard at least one-and-a-half metres (1.5 m) above the ground is a good place to store medicines.

Do not use this medicine after the expiry date which is stated on the label or carton. The expiry date refers to the last day of that month.

Do not store Haldol, or any other medicine, in the bathroom or near a sink. Do not leave medicines in the car or on window sills. Heat and dampness can destroy some medicines.

Disposal

If your doctor tells you to stop using Haldol Injection, or your medicine has passed its expiry date, ask your pharmacist what to do with any medicine which may be left over.

Product Description

What it looks like

Haldol Oily Injection is a slightly amber and viscous solution, and comes in 1 mL or 3 mL amber glass ampoules. Each pack contains 5 ampoules.

Ingredients

Each mL of Haldol Injection contains

- 50 mg haloperidol (as decanoate) as the active ingredient
- other ingredients: sesame oil vehicle, benzyl alcohol

Contains sesame seed products.

Sponsor

JANSSEN-CILAG Pty Ltd

1-5 Khartoum Road Macquarie Park
NSW 2113

Australia

Telephone: 1800 226 334

NZ Office: Auckland New Zealand

Telephone: 0800 800 806

Registration number

The Australian Registration Numbers are:

Haldol Decanoate 50 mg/1 mL

Injection - AUST R 13302

Haldol Decanoate 150 mg/3 mL

Injection - AUST R 46901

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