

HALDOL(R) Injection

Haloperidol decanoate

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 is used to control the symptoms of mental illnesses with disturbances in thinking, feelings and behaviour.

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

Your doctor may have prescribed HALDOL for another use. Ask your doctor 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.

Do not use HALDOL if you:

- * have severe drowsiness and slowness due to illness or the use of alcohol or medicine
- * have severe depression
- * have or have ever had muscle stiffness, restricted or uncontrollable movement due to certain medical conditions, such as Parkinson's disease
- * have an allergy to HALDOL or any of the ingredients. See Product Description at the end of this leaflet for a list of ingredients.

Do not use HALDOL if the packaging is torn or shows signs of tampering. Do not use HALDOL 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
- * are breast feeding or wish to breastfeed
- * suffer from dementia-related psychosis (loss of contact with reality and inability to think and judge clearly, resulting from a general decline in all areas of mental ability)

- * have or have ever had a heart problem, including an unusual heart beat and a fast heart beat, 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 tardive dyskinesia (a reaction to some medicines with uncontrolled movements of the tongue, mouth, cheeks or jaws which may progress to the arms and legs)
- * have or have ever had neuroleptic malignant syndrome (a reaction to some medicines with a sudden increase in body temperature, extremely high blood pressure and severe convulsions)
- * have or have ever had epilepsy or any other condition that can cause fits (for example, during a cure for a drinking problem or as a result of brain damage)
- * have or have ever had liver disease
- * have a very active thyroid gland
- * experience a significant increase in weight while taking other antipsychotic medications. Clinically significant weight gain has also been reported in patients taking 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:

- * itraconazole, nefazodone, buspirone, venlafaxine, alprazolam, fluvoxamine, quinidine, fluoxetine, sertraline, chlorpromazine and promethazine
- * ketoconazole (an antifungal medication) and paroxetine (a medication used to treat depression)
- * 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
- * methyl dopa (used to lower high blood pressure)
- * Certain cough and cold preparations and weight reduction medicines containing substances such as adrenaline
- * medicines that prevent adrenaline working, such as guanethidine

- * antibiotics such as rifampicin
- * anticholinergic drugs (used to prevent travel sickness, treat Parkinson's Disease or relieve stomach cramps or spasms)
- * certain medicines used to treat Parkinson's disease, such as levodopa (L-dopa)
- * certain medicines for depression
- * carbamazepine, phenobarbital (used to treat epilepsy)
- * lithium (used to treat episodes of mood swing)
- * anticoagulants (used to slow blood clotting).

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.

Effects on driving and operating machinery

HALDOL can affect your alertness and ability to drive and operate machinery. Do not drive or operate machinery until your doctor says it is safe.

Do not drink alcohol. HALDOL can increase the effects of alcohol.

Using HALDOL

How it is given:

HALDOL will be injected by your doctor into a muscle in the buttocks. It is usually given every four weeks, however your doctor may lengthen or shorten this time.

HALDOL should not be given into a vein.

Your doctor will decide how much HALDOL you need. 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.

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.

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.

Do this even if there are no signs of discomfort or poisoning. 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.

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.
- * Seek your doctor's advice before changing or stopping HALDOL

treatment.

- * Tell your doctor if you become pregnant while using HALDOL.
- * If you are about to start taking a new medicine, tell your doctor and pharmacist that you are using HALDOL.

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
- * constipation
- * increased salivation
- * nausea or vomiting
- * changes in sex drive in both men and women
- * weight gain
- * muscle rigidity
- * redness, burning or pain at the site HALDOL is given
- * blurred vision
- * low blood pressure which may cause dizziness or headache
- * shaking or tremors
- * 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

- * uncontrollable muscle spasms affecting the eyes, head, neck and body
- * 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, swelling of the face, lips or throat.
- * a sudden increase in body temperature, extremely high blood pressure, stiff muscles, decreased mental alertness or fits (seizures).
- * fast or unusual heart beat.

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 degrees C. Do not freeze or refrigerate it. 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 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 Injection is a slightly amber solution and comes in 1 mL or 3 mL amber glass ampoules. Each pack contains 5 ampoules.

The Australian Registration Numbers are:

HALDOL 50mg/1mL Injection - AUST R 13302

HALDOL 150mg/3mL Injection - AUST R 46901

Ingredients

Each mL of HALDOL Injection contains

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

Sponsor

JANSSEN-CILAG Pty Ltd
1-5 Khartoum Road North Ryde
NSW 2113

Australia

Telephone: 1800 226 334

NZ Office: Auckland New Zealand

Telephone: 0800 800 806

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