

# Haldol® Decanoate

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## Consumer Medicine Information (CMI) summary

The [full CMI](#) on the next page has more details. If you are worried about using this medicine, speak to your doctor or pharmacist.

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### 1. Why am I using Haldol?

Haldol Decanoate (Haldol) contains the active ingredient haloperidol (as haloperidol decanoate). Haldol is used in adults whose condition has previously been treated with haloperidol taken by mouth.

For more information, see Section [1. Why am I using Haldol?](#) in the full CMI.

### 2. What should I know before I am given Haldol?

Do not use if you have ever had an allergic reaction to Haldol or any of the ingredients listed at the end of the CMI.

**Talk to your doctor if you have any other medical conditions, take any other medicines, are pregnant or plan to become pregnant or are breastfeeding.**

For more information, see Section [2. What should I know before I am given Haldol?](#) in the full CMI.

### 3. What if I am taking other medicines?

Some medicines may interfere with Haldol and affect how it works.

A list of these medicines is in Section [3. What if I am taking other medicines?](#) in the full CMI.

### 4. How is Haldol given?

- Haldol will be given as an injection by your doctor or nurse into a muscle in the buttocks.
- It is usually given every four weeks, however your doctor may lengthen or shorten this time.

More instructions can be found in Section [4. How is Haldol given?](#) in the full CMI.

### 5. What should I know while using Haldol?

#### Things you should do

- Remind any doctor, dentist or pharmacist you visit that you are using Haldol.
- Be sure to keep all of your doctor's appointments so that

|   |   |
|---|---|
|   | <p>your progress can be checked.</p> <ul style="list-style-type: none"> <li>• Always follow your doctor's instructions carefully.</li> <li>• Tell your doctor if you become pregnant while using Haldol</li> </ul>  |
| <p><b>Things you should not do</b></p>  | <ul style="list-style-type: none"> <li>• Do not use Haldol to treat any other complaint unless your doctor says so.</li> <li>• Do not give this medicine to anyone else, even if their symptoms seem similar to yours.</li> </ul>   |
| <p><b>Driving or using machines</b></p> | <ul style="list-style-type: none"> <li>• Do not drive or operate any tools or machinery until your doctor says it is safe.</li> <li>• Haldol can cause dizziness in some people, and affect your alertness and ability to drive and operate machinery, particularly when you first start using it, or after a high dose.</li> </ul> |

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|------------------------------------|---|
| <b>Drinking alcohol</b>            | <ul style="list-style-type: none"> <li>• Do not drink alcohol.</li> </ul>   |
| <b>Looking after your medicine</b> | <ul style="list-style-type: none"> <li>• Store below 25°C, in a cool dry place. Protect it from light.</li> </ul> |

For more information, see Section [5. What should I know while using Haldol?](#) in the full CMI.

## **6. Are there any side effects?**

Common side effects include: uncontrollable twitching or jerking movements, tremors, disease of the brain affecting movement, resulting in trembling, rigid posture, slow movements and a shuffling, unbalanced walk (parkinsonism), drowsiness or sleepiness, lack of normal facial expressions, restlessness or difficulty sitting still, dry mouth, constipation, increased salivation, problems having sex, injection site reaction, weight increase. Serious side effects include difficulty in breathing, or deeper and faster breathing, allergic reactions 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) and fast or unusual heartbeat. For more information, including what to do if you have any side effects, see Section [6. Are there any side effects?](#) in the full CMI.

# Haldol® Decanoate

**Active ingredient:** *haloperidol decanoate*

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## Consumer Medicine Information (CMI)

This leaflet provides important information about using Haldol. **You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about using Haldol.**

**Where to find information in this leaflet:**

- [1. Why am I using Haldol?](#)
- [2. What should I know before I use Haldol?](#)
- [3. What if I am taking other medicines?](#)
- [4. How do I use Haldol?](#)
- [5. What should I know while using Haldol?](#)
- [6. Are there any side effects?](#)
- [7. Product details](#)

## 1. Why am I using Haldol?

**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.

## 2. What should I know before I use Haldol?

### Warnings

#### Do not use Haldol if you:

- you are allergic to haloperidol decanoate, or any of the ingredients listed at the end of this leaflet.
- Always check the ingredients to make sure you can use this medicine.
- 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).

#### Check with your doctor if you:

- take any medicines for any other condition
- 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.
- 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).

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them. See additional information under Section [6. Are there any side effects?](#)

## **Pregnancy and breastfeeding**

Check with your doctor if you are pregnant or intend to become pregnant.

Talk to your doctor if you are breastfeeding or intend to breastfeed.

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

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.

## **Use in Children and Adolescents**

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.

### 3. What if I am taking other medicines?

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

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.

#### **Some medicines may interfere with Haldol and affect how it works:**

- 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, tranquilisers or strong pain relief medicine
- medicines used to lower high blood pressure and heart conditions (such as methyldopa, bepridil)
- 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 (for pain relief or to treat drug addiction).

- medicines used for malaria (such as halofantrine)
- medicines used for cancer (such as toremifene and vandetanib)

**Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect Haldol.**

## **4. How do I use Haldol?**

### **How much to use**

- 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. 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.

### **When to use Haldol**

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

## **How to inject Haldol**

- 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.

## **If you forget to use Haldol**

If you miss your 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 Haldol**

If you think that you have been given too much Haldol, you may need urgent medical attention.

### **You should immediately:**

- phone the Poisons Information Centre (by calling **13 11 26 in Australia or 0800 POISON or 0800 764 766 in New Zealand**), or
- contact your doctor, or
- go to the Emergency Department at your nearest hospital.

### **You should do this even if there are no signs of discomfort or poisoning.**

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.

## **5. What should I know while using Haldol?**

### **Things you should 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.

### **Call your doctor straight away 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)

Remind any doctor, dentist or pharmacist you visit that you are using Haldol.

## **Things you should 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.

## **Driving or using machines**

**Do not drive or use any machines or tools until your doctor says its safe.**

Haldol may cause dizziness in some people.

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

## **Drinking alcohol**

**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

## **Looking after your medicine**

- Keep Haldol in the pack until it is time to use it
- Store below 25°C in a cool dry place. Protect it from light.

Follow the instructions in the carton on how to take care of your medicine properly.

Store it in a cool dry place away from moisture, heat or sunlight; for example, do not store it:

- in the bathroom or near a sink, or
- in the car or on window sills.

**Keep it where young children cannot reach it.**

A locked cupboard at least one-and-a-half metres (1.5 m) above the ground is a good place to store medicines.

## **When to discard your medicine**

Do not use this medicine 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. The expiry date refers to the last day of that month.

## **Getting rid of any unwanted medicine**

If you no longer need to use this medicine or it is out of date, take it to any pharmacy for safe disposal.

## **6. Are there any side effects?**

All medicines can have side effects. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention.

See the information below and, if you need to, ask your doctor or pharmacist if you have any further questions about side effects.



## Less serious side effects

| Less serious side effects   | What to do  |
|---|---|
| <p><b>General</b></p> <ul style="list-style-type: none"> <li>• low body temperature</li> <li>• weight gain or weight loss</li> <li>• redness, burning or pain at the site</li> </ul> <p>Haldol is given including collection of pus</p> | <p><b>Speak to your doctor if you have any of these less serious side effects and they worry you.</b></p> |

| Less serious side effects   | What do they do |
|---|-----------------|
| <p>at the site</p> <ul style="list-style-type: none"> <li>• being unable to pass urine or empty the bladder completely</li> <li>• swelling caused by fluid build up in the body</li> </ul> <p><b>Psychiatric related</b></p> <ul style="list-style-type: none"> <li>• restlessness or difficulty</li> </ul> | <p>S</p>        |

| Less serious side effects  | What do they do |
|--|-----------------|
| sitting still<br><ul style="list-style-type: none"> <li>• difficulty sleeping</li> <li>• feeling agitated, confused or depressed</li> <li>• Serious mental health problems such as believing things that are not true (delusions) or seeing or hearing things that are not there (hallucinations)</li> </ul> |                 |

| Less serious side effects   | What do so do |
|---|---------------|
| <p>something that are not there (hallucinations)</p> <p><b>Gastrointestinal related</b></p> <ul style="list-style-type: none"> <li>• constipation</li> <li>• dry mouth</li> <li>• increased salivation</li> <li>• nausea or vomiting</li> </ul> <p><b>Nervous System related</b></p> <ul style="list-style-type: none"> <li>• drowsiness or sleepiness</li> <li>• lack of normal</li> </ul> |               |

| Less serious side effects   | What do you do                   |
|---|----------------------------------|
| <p>facial expressions that some look like a mask</p> <ul style="list-style-type: none"> <li>• uncontrolled twitches or jerking movements of the arms and legs worried like movements of the tongue or other uncontrolled movements</li> </ul> | <p>stop</p> <p>able</p> <p>d</p> |

| Less serious side effects   | What do they do |
|---|-----------------|
| <p>of the mouth, tongue, cheeks or jaws which may progress to the arms and legs</p> <ul style="list-style-type: none"> <li>• shaking or tremor</li> <li>• disease of the brain affected movement results in tremor, rigidity</li> </ul> |                 |

|   |   |
|---|---|
| <p><b>Less serious side effects</b></p>   | <p><b>What do side effects do</b></p>   |
| <p>post slow mov and a shuf unba walk (parl sm)</p>   |   |
| <p><b>Repro related</b></p> <ul style="list-style-type: none"> <li>• diffic getti and keep an erec (imp pain and pers erec</li> <li>• enla brea in men</li> </ul> | <p><b>Speake- to your doctor if you have any of these , less serious side effects and they worry you.</b></p> |

| Less serious side effects  | What do they do |
|--|-----------------|
| <ul style="list-style-type: none"> <li>• problems with menstrual periods such as having no periods, painful periods, long and heavy periods or changes in menstrual cycle</li> <li>• unexpected products of breast milk</li> </ul> |                 |



| Less serious side effects  | What do they do |
|--|-----------------|
| <ul style="list-style-type: none"> <li>• headache</li> <li>• drowsiness</li> <li>• dizziness</li> <li>• changes in sex drive in both men and women</li> <li>• problems having sex</li> </ul> <p><b>Skin-related</b></p> <ul style="list-style-type: none"> <li>• problems with skin such as flaking or peeling of skin.</li> </ul> |                 |

| Less serious side effects  | What do they do |
|--|-----------------|
| <p>itching<br/>rash<br/>hives<br/>sensitivity to sunlight</p> <ul style="list-style-type: none"> <li>• excessive sweating</li> </ul> <p><b>Muscle related</b></p> <ul style="list-style-type: none"> <li>• muscle stiffness or weakness</li> <li>• abnormal muscle tension</li> <li>• joint stiffness</li> <li>• breakdown of muscle tissue (rhabdomyolysis)</li> <li>• being unable to</li> </ul> |                 |

metal-

olysis)

| Less serious side effects   | What do they do |
|---|-----------------|
| <p>mov<br/>diffic<br/>oper<br/>the<br/>mou</p> <ul style="list-style-type: none"> <li>• unco<br/>mus<br/>spas<br/>affec<br/>the<br/>eyes<br/>head<br/>neck<br/>and<br/>body</li> </ul> <p><b>Eye-related</b></p> <ul style="list-style-type: none"> <li>• Visio<br/>prob<br/>such<br/>as<br/>blurr<br/>visio</li> </ul> <p><b>Blood related</b></p> | <p>ple</p>      |

| Less serious side effects  | What do they do |
|--|-----------------|
| <ul style="list-style-type: none"> <li>• low blood pressure which may cause dizziness or headache</li> <li>• problems with liver such as jaundice, abnormal blood tests of the liver, liver failure</li> </ul> |                 |

## Serious side effects

| Serious side effects   | What to do   |
|--|--|
| <ul style="list-style-type: none"> <li>• Difficult in breathing or deep and fast breathing</li> <li>• Allergic reactions with signs such as skin rash, itching, shortness of breath and/or swelling of the face</li> </ul> | <p><b>Call your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you notice any of these serious side effects.</b></p> |

| Serious side effects   | What to do |
|--|------------|
| <p>lips or throat that may lead to difficulty breathing or swallowing</p> <ul style="list-style-type: none"> <li>• A sudden increase in body temperature, extremely high blood pressure, stiff muscles, decreased mental alertness or fits (seizures)</li> </ul> |            |

| Serious side effects   | What to do |
|--|------------|
| <ul style="list-style-type: none"> <li>• Abnormal heart rhythm (in ECG) fast or unusual heart</li> </ul> |            |

**Tell your doctor or pharmacist if you notice anything else that may be making you feel unwell.**

Other side effects not listed here may occur in some people.

## **Reporting side effects**

After you have received medical advice for any side effects you experience, you can report side effects to the Therapeutic Goods Administration online at [www.tga.gov.au/reporting-problems](http://www.tga.gov.au/reporting-problems). By reporting side effects, you can help provide more information on the safety of this medicine.

**Always make sure you speak to your doctor or pharmacist before you decide to stop taking any of your medicines.**

## 7. Product details

This medicine is only available with a doctor's prescription.

### What Haldol contains

|   |  |
|---|--|
| <b>Active ingredient<br/>(main ingredient)</b>      | <b>haloperidol (as<br/>decanoate)</b>            |
| <b>Other ingredients<br/>(inactive ingredients)</b> | Sesame oil vehicle, benzyl alcohol               |
| <b>Potential allergens</b>                          | Contains sesame seed products and benzyl alcohol |

**Do not take this medicine if you are allergic to any of these ingredients.**

### What Haldol looks like

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

50 mg/1 mL Injection - AUST R 13302

150 mg/3 mL Injection - AUST R 46901.



## **Who distributes Haldol**

Clinect Pty Ltd

120-132 Atlantic Drive

Keysborough VIC 3173

Australia

Free Call Australia: 1800 899 005

Free Call New Zealand: 0800 138 803

This leaflet was prepared in October 2024.