

Package leaflet: Information for the patient

HALDOL® Decanoate 50 mg/ml solution for injection **HALDOL® Decanoate 100 mg/ml solution for injection**

haloperidol

Read all of this leaflet carefully before you start using this medicine because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor, pharmacist or nurse.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What Haldol Decanoate is and what it is used for
2. What you need to know before you are given Haldol Decanoate
3. How to use Haldol Decanoate
4. Possible side effects
5. How to store Haldol Decanoate
6. Contents of the pack and other information

1. What Haldol Decanoate is and what it is used for

The name of your medicine is Haldol Decanoate.

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

Haldol Decanoate 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.

2. What you need to know before you are given Haldol Decanoate

Do not use Haldol Decanoate if:

- You are allergic to haloperidol or any of the other ingredients of this medicine (listed in section 6)
- You are allergic to sesame oil. Haldol Decanoate contains sesame oil. See ‘Haldol Decanoate contains’ below
- You are less aware of things around you or your reactions become unusually slow
- You have Parkinson’s disease
- You have a type of dementia called ‘Lewy body dementia’

- You have progressive supranuclear palsy (PSP)
- You have a heart condition called ‘prolonged QT interval’, or any other problem with your heart rhythm that shows as an abnormal tracing on an ECG (electrocardiogram)
- You have heart failure or recently had a heart attack
- You have a low level of potassium in your blood, which has not been treated
- You take any of the medicines listed under ‘Other medicines and Haldol Decanoate – Do not use Haldol Decanoate if you are taking certain medicines for’.

This medicine must not be used if any of the above applies to you. If you are not sure, talk to your doctor, pharmacist or nurse before being given Haldol Decanoate.

Warnings and precautions

Serious side effects

Haldol Decanoate can cause problems with the heart, problems controlling body or limb movements and a serious side effect called ‘neuroleptic malignant syndrome’. It can also cause severe allergic reactions and blood clots. You must be aware of serious side effects while you are using Haldol Decanoate because you may need urgent medical treatment. See ‘Look out for serious side effects’ in section 4.

Elderly people and people with dementia

A small increase in deaths and strokes has been reported for elderly people with dementia who are taking antipsychotic medicines. Talk to your doctor before being given Haldol Decanoate if you are elderly, particularly if you have dementia.

Talk to your doctor if you have:

- A slow heartbeat, heart disease or anyone in your close family has died suddenly of heart problems
- Low blood pressure, or feel dizzy upon sitting up or standing up
- A low level of potassium or magnesium (or other ‘electrolyte’) in your blood. Your doctor will decide how to treat this
- Ever had bleeding in the brain, or your doctor has told you that you are more likely than other people to have a stroke
- Epilepsy or have ever had fits (convulsions)
- Problems with your kidneys, liver or thyroid gland
- A high level of the hormone 'prolactin' in your blood, or cancer that may be caused by high prolactin levels (such as breast cancer)
- A history of blood clots, or someone else in your family has a history of blood clots
- Depression.

You may need to be more closely monitored, and the amount of Haldol Decanoate you are given may have to be altered.

If you are not sure if any of the above applies to you, talk to your doctor or nurse before you are given Haldol Decanoate.

Medical check ups

Your doctor may want to take an electrocardiogram (ECG) before or during your treatment with Haldol Decanoate. The ECG measures the electrical activity of your heart.

Blood tests

Your doctor may want to check the levels of potassium or magnesium (or other ‘electrolyte’) in your blood before or during your treatment with Haldol Decanoate.

Children and adolescents

Haldol Decanoate should not be used in children and adolescents below 18 years. This is because it has not been studied in these age groups.

Other medicines and Haldol Decanoate

Tell your doctor, pharmacist or nurse if you are taking, have recently taken or might take any other medicines.

Do not use Haldol Decanoate if you are taking certain medicines for:

- Problems with your heartbeat (such as amiodarone, dofetilide, disopyramide, dronedarone, ibutilide, quinidine and sotalol)
- Depression (such as citalopram and escitalopram)
- Psychoses (such as fluphenazine, levomepromazine, perphenazine, pimozide, prochlorperazine, promazine, sertindole, thiorizadine, trifluoperazine, triflupromazine and ziprasidone)
- Bacterial infections (such as azithromycin, clarithromycin, erythromycin, levofloxacin, moxifloxacin and telithromycin)
- Fungal infections (such as pentamidine)
- Malaria (such as halofantrine)
- Nausea and vomiting (such as dolasetron)
- Cancer (such as toremifene and vandetanib).

Also tell your doctor if you are taking bepridil (for chest pain or to lower blood pressure) or methadone (a pain killer or to treat drug addiction).

These medicines may make heart problems more likely, so talk to your doctor if you are taking any of these and do not use Haldol Decanoate (see 'Do not use Haldol Decanoate if').

Special monitoring may be needed if you are using lithium and Haldol Decanoate at the same time. Tell your doctor straight away and stop taking both medicines if you get:

- Fever you can't explain or movements you can't control
- Confused, disoriented, a headache, balance problems and feel sleepy.

These are signs of a serious condition.

Certain medicines may affect the way that Haldol Decanoate works or may make heart problems more likely

Tell your doctor if you are taking:

- Alprazolam or buspirone (for anxiety)
- Duloxetine, fluoxetine, fluvoxamine, nefazodone, paroxetine, sertraline, St John's Wort (*Hypericum perforatum*) or venlafaxine (for depression)
- Bupropion (for depression or to help you stop smoking)
- Carbamazepine, phenobarbital or phenytoin (for epilepsy)
- Rifampicin (for bacterial infections)
- Itraconazole, posaconazole or voriconazole (for fungal infections)
- Ketoconazole tablets (to treat Cushing's syndrome)
- Indinavir, ritonavir or saquinavir (for human immunodeficiency virus or HIV)
- Chlorpromazine or promethazine (for nausea and vomiting)
- Verapamil (for blood pressure or heart problems).

Also tell your doctor if you are taking any other medicines to lower blood pressure, such as water tablets (diuretics).

Your doctor may have to change your dose of Haldol Decanoate if you are taking any of these medicines.

Haldol Decanoate can affect the way the following types of medicine work

Tell your doctor if you are taking medicines for:

- Calming you down or helping you to sleep (tranquillisers)
- Pain (strong pain killers)
- Depression ('tricyclic antidepressants')
- Lowering blood pressure (such as guanethidine and methyldopa)
- Severe allergic reactions (adrenaline)
- Attention deficit hyperactivity disorder (ADHD) or narcolepsy (known as 'stimulants')
- Parkinson's disease (such as levodopa)
- Thinning the blood (phenindione).

Talk to your doctor or nurse before being given Haldol Decanoate if you are taking any of these medicines.

Haldol Decanoate and alcohol

Drinking alcohol while you are using Haldol Decanoate might make you feel sleepy and less alert. This means you should be careful how much alcohol you drink. Talk to your doctor about drinking alcohol while using Haldol Decanoate, and let your doctor know how much you drink.

Pregnancy, breast-feeding and fertility

Pregnancy – if you are pregnant, think you may be pregnant or are planning to have a baby, ask your doctor for advice. Your doctor may advise you not to use Haldol Decanoate while you are pregnant.

The following problems may occur in newborn babies of mothers that use Haldol Decanoate 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.

The exact frequency of these problems is unknown. If you used Haldol Decanoate while pregnant and your baby develops any of these side effects, contact your doctor.

Breast-feeding – talk to your doctor if you are breast-feeding or planning to breast-feed. This is because small amounts of the medicine may pass into the mother's milk and on to the baby. Your doctor will discuss the risks and benefits of breast-feeding while you are using Haldol Decanoate.

Fertility – Haldol Decanoate may increase your levels of a hormone called 'prolactin', which may affect fertility in men and women. Talk to your doctor if you have any questions about this.

Driving and using machines

Haldol Decanoate can affect your ability to drive and use tools or machines. Side effects, such as feeling sleepy, may affect your alertness, particularly when you first start using it or after a high dose. Do not drive or use any tools or machines without discussing this with your doctor first.

Haldol Decanoate contains benzyl alcohol and sesame oil

This medicine contains 15 mg of benzyl alcohol in each ml of the solution. Benzyl alcohol may cause allergic reactions. Ask your doctor or pharmacist for advice if you have liver or kidney disease, or if you are pregnant or breast-feeding. This is because large amounts of benzyl alcohol can build-up in your body and may cause side effects (called 'metabolic acidosis').

This medicine also contains sesame oil, which may rarely cause severe allergic reactions.

3. How to use Haldol Decanoate

How much medicine will you be given

Your doctor will decide how much Haldol Decanoate you need and for how long. Your doctor will adjust the dose to suit you, and may also give you a type of haloperidol that you take by mouth. Your dose of haloperidol decanoate will depend on:

- Your age
- Whether you have problems with your kidneys or liver
- How you have reacted to haloperidol in the past
- Other medicines you are taking.

Adults

- Your starting dose will normally be between 25 mg and 150 mg.
- Your doctor may adjust the dose by up to 50 mg every 4 weeks to find the dose that suits you best (normally between 50 mg and 200 mg every 4 weeks).
- You will not be given more than 300 mg every 4 weeks.

Elderly people

- Elderly people will normally start on a lower dose, usually 12.5 mg to 25 mg every 4 weeks.
- The dose may be adjusted until the doctor finds the dose that suits you best (normally between 25 mg and 75 mg every 4 weeks).
- You will only be given a higher dose than 75 mg every 4 weeks if your doctor decides it is safe to do so.

How Haldol Decanoate is given

Haldol Decanoate will be given by a doctor or nurse. It is for intramuscular use, and is given as an injection deep into a muscle. A single dose of Haldol Decanoate will normally last for 4 weeks. Haldol Decanoate must not be injected into a vein.

If you have too much Haldol Decanoate

A doctor or nurse will give this medicine to you, so it is unlikely that you will be given too much. If you are worried, tell the doctor or nurse.

If you miss a dose or stop using Haldol Decanoate

You should not stop this medicine unless told to do so by your doctor as your symptoms may return. If you miss an appointment, contact your doctor right away to make a new appointment.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

Look out for serious side effects

Tell your doctor or nurse straight away if you notice or suspect any of the following. You may need urgent medical treatment.

Problems with the heart:

- Abnormal heart rhythm – this stops the heart working normally and may cause loss of consciousness
- Abnormally fast heartbeat
- Extra heart beats.

Heart problems are uncommon in people using Haldol Decanoate (may affect up to 1 in 100 people). Sudden deaths have occurred in patients using this medicine, but the exact frequency of these deaths is unknown. Cardiac arrest (the heart stops beating) has also occurred in people taking antipsychotic medicines.

A serious problem called ‘neuroleptic malignant syndrome’. This causes a high fever, severe muscle stiffness, confusion and loss of consciousness. The exact frequency of this side effect in people using Haldol Decanoate is unknown.

Problems controlling movements of the body or limbs (extrapyramidal disorder), such as:

- Movements of the mouth, tongue, jaw and sometimes limbs (tardive dyskinesia)
- Feeling restless or difficulty sitting still, increased body movements
- Slow or reduced body movements, jerking or twisting movements
- Muscle tremors or stiffness, a shuffling walk
- Being unable to move
- Lack of normal facial expression that sometimes looks like a mask.

These are very common in people using Haldol Decanoate (may affect more than 1 in 10 people). If you get any of these effects, you may be given an additional medicine.

Severe allergic reaction that may include:

- A swollen face, lips, mouth, tongue or throat
- Difficulty swallowing or breathing
- Itchy rash (hives).

The exact frequency of an allergic reaction in people using Haldol Decanoate is unknown.

Blood clots in the veins, usually in the legs (deep vein thrombosis or DVT). These have been reported in people taking antipsychotic medicines. The signs of a DVT in the leg include swelling, pain and redness in the leg, but the clot may move to the lungs causing chest pain and difficulty in breathing. Blood clots can be very serious, so tell your doctor straight away if you notice any of these problems.

Tell your doctor straight away if you notice any of the serious side effects above.

Other side effects

Tell your doctor if you notice or suspect any of the following side effects.

Common (may affect up to 1 in 10 people):

- Depression
- Difficulty sleeping or feeling sleepy
- Constipation
- Dry mouth or increased saliva
- Problems having sex
- Irritation, pain or collection of pus (abscess) where the injection is given
- Weight gain.

Uncommon (may affect up to 1 in 100 people):

- Abnormal muscle tension
- Headache
- Upward movement of the eyes or fast eye movements that you cannot control
- Problems with vision, such as blurred vision.

The following side effects have also been reported, but their exact frequency is unknown:

- 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)
- Feeling agitated or confused
- Fits (seizures)
- Feeling dizzy, including upon sitting up or standing up
- Low blood pressure
- Problems that could cause difficulty breathing, such as:
 - Swelling around the voice box, or brief spasm of the vocal cords that affects speaking
 - Narrowed airways in the lungs
 - Being short of breath
- Nausea, vomiting
- Changes in the blood, such as:
 - Effects on blood cells – low number of all types of blood cells, including severe decreases in white blood cells and low number of ‘platelets’ (cells that help blood to clot)
 - High level of certain hormones in the blood – ‘prolactin’ and ‘antidiuretic hormone’ (syndrome of inappropriate antidiuretic hormone secretion)
 - Low level of sugar in the blood
- Changes that show up in blood tests of the liver and other liver problems, such as:
 - Yellowing of the skin or whites of the eyes (jaundice)
 - Inflamed liver
 - Sudden liver failure
- Decreased bile flow in the bile duct
- Skin problems, such as:
 - Rash or itching
 - Increased sensitivity to sunlight
 - Flaking or peeling skin
 - Inflamed small blood vessels, leading to a skin rash with small red or purple bumps
- Excessive sweating
- Breakdown of muscle tissue (rhabdomyolysis)
- Muscle spasms, twitching or contractions that you cannot control, including a spasm in the neck causing the head to twist to one side
- Difficulty or being unable to open the mouth
- Stiff muscles and joints
- Being unable to pass urine or empty the bladder completely
- Persistent and painful erection of the penis
- Difficulty getting and keeping an erection (impotence)
- Loss of sex drive or decreased sex drive
- Changes in menstrual cycle (periods), such as no periods, or long, heavy, painful periods
- Breast problems, such as:
 - Pain or discomfort
 - Unexpected production of breast milk
 - Enlarged breasts in men
- Swelling caused by fluid build up in the body
- High or low body temperature
- Problems walking
- Weight loss.

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via:

HPRA Pharmacovigilance,
Earlsfort Terrace,
IRL - Dublin 2,
Tel: +353 1 6764971,
Fax: +353 1 6762517,
Website: www.hpra.ie,
E-mail: medsafety@hpra.ie

By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Haldol Decanoate

Keep this medicine out of the sight and reach of children.

Haldol Decanoate should not be used after the expiry date which is stated on the label and the carton <after EXP>. The expiry date refers to the last day of that month.

Store in the original package to protect from light.

6. Contents of the pack and other information

What Haldol Decanoate contains

50 mg/ml solution:

The active substance is haloperidol. Each ml of the solution for injection contains 70.52 mg of haloperidol decanoate, equivalent to 50 mg of haloperidol base. The other ingredients are benzyl alcohol and sesame oil.

100 mg/ml solution:

The active substance is haloperidol. Each ml of the solution for injection contains 141.04 mg of haloperidol decanoate, equivalent to 100 mg of haloperidol base. The other ingredients are benzyl alcohol and sesame oil.

What Haldol Decanoate looks like and contents of the pack

50 mg/ml solution:

Haldol Decanoate is a slightly amber, slightly viscous solution, with no visible particles. It is supplied in amber glass ampoules containing 1 ml of solution in packs of 1, 3 or 5 ampoules, or 3 ml of solution in packs of 1, 5 or 50 (10 packs of 5) ampoules.

100 mg/ml solution:

Haldol Decanoate is a slightly amber, slightly viscous solution, with no visible particles. It is supplied in amber glass ampoules containing 1 ml of solution in packs of 1 or 5 ampoules.

Not all pack sizes may be marketed.

Marketing Authorisation Holder

Essential Pharma Limited,
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Manufacturer

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Torrile, Parma, Italy.

This medicinal product is authorised in the Member States of the EEA under the following names:

Austria:	Haldol Decanoat
Belgium, Cyprus, France, Italy, Luxembourg, Netherlands:	Haldol Decanoas
Ireland, Malta, United Kingdom:	Haldol Decanoate
Denmark:	Serenase Dekanoat
Finland:	Seranase Depot
Germany:	Haldol-Janssen Decanoat Depot
Greece:	Aloperidin Decanoas
Iceland, Norway, Sweden:	Haldol Depot
Portugal:	Haldol Decanoato

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