

**Package leaflet: Information for the patient
Haloperidol 5mg/ml Solution for Injection**

Read all of this leaflet carefully before you are given 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 or nurse.
- If you get any side effects, talk to your doctor or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

The name of your medicine is Haloperidol 5mg/ml Solution for Injection. It will be referred to as Haloperidol Injection for ease hereafter.

What is in this leaflet

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

1. What Haloperidol Injection is and what it is used for

Haloperidol Injection contains the active substance haloperidol. This belongs to a group of medicines called ‘antipsychotics’.

Haloperidol Injection is used in adults for illnesses affecting the way you think, feel or behave. These include mental health problems (such as schizophrenia and bipolar disorder) and behavioural problems.

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.

Haloperidol Injection is also used in adults:

- To help control movements in Huntington’s disease
- To prevent or treat nausea and vomiting (feeling and being sick) after surgery.

Haloperidol Injection may be used on its own or with other medicine, and is sometimes used when other medicines or treatments have not worked, caused unacceptable side effects, or cannot be taken by mouth.

2. What you need to know before you are given Haloperidol Injection

Do not use Haloperidol Injection if:

- you are allergic to haloperidol or any of the other ingredients of this medicine (listed in section 6)
- 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 Haloperidol – Do not use Haloperidol injection 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 haloperidol injection.

Warnings and precautions

Serious side effects

Haloperidol injection 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 Haloperidol injection 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 Haloperidol injection if you are elderly, particularly if you have dementia.

Talk to your doctor if you have:

- A slow heart beat, 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, or you have bipolar disorder and start to feel depressed.

You may need to be more closely monitored, and the amount of Haloperidol injection 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 Haloperidol injection.

Medical check ups

Your doctor may want to take an electrocardiogram (ECG) before or during your treatment with Haloperidol injection. 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 electrolytes) in your blood before or during your treatment with Haloperidol injection.

Children and adolescents

Haloperidol Injection should not be used in children and adolescents below 18 years. This is because it has not been studied in this age group.

Other medicines and Haloperidol Injection

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

Do not take haloperidol injection if you are taking certain medicines for:

- Problems with your heart beat (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 take haloperidol injection (see 'Do not take haloperidol injection if').

Special monitoring may be needed if you are using lithium and haloperidol injection 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 haloperidol injection 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 haloperidol injection if you are taking any of these medicines.

Haloperidol injection 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 haloperidol injection if you are taking any of these medicines.

Haloperidol Injection and alcohol

Drinking alcohol while you are using haloperidol injection 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 haloperidol injection, 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 Haloperidol injection while you are pregnant.

The following problems may occur in newborn babies of mothers that use Haloperidol injection 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 haloperidol injection 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 Haloperidol injection.

Fertility – haloperidol injection 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

Haloperidol injection 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.

Haloperidol Injection contains Sodium

This medicine contains less than 1 mmol sodium (23mg) per dose, i.e. is essentially sodium free.

3. How you will be given Haloperidol Injection

Always take this medicine exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure.

How much medicine will you be given

Your doctor will decide how much Haloperidol injection you need and for how long. It may be some time before you feel the full effect of the medicine. Your doctor will normally give you a low dose to start and then adjust the dose to suit you.

Your dose of haloperidol will depend on:

- Your age
- What condition you are being treated for
- Whether you have problems with your kidneys or liver
- Other medicines you are taking.

Adults

- Your starting dose will normally be between 1 and 5 mg.
- You may be given extra doses, normally 1 to 4 hours apart.
- You will not be given more than a total of 20 mg each day.

Elderly people

- Elderly people will normally start on half the lowest adult dose.
- The dose will then be adjusted until the doctor finds the dose that suits you best.
- You will not be given more than a total of 5 mg each day unless your doctor decides a higher dose is needed.

How Haloperidol injection is given

Haloperidol injection will be given by a doctor or nurse. It is for intramuscular use, and is given as an injection into a muscle.

If you miss a dose or have too much Haloperidol Injection

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

If you stop using Haloperidol Injection

Unless your doctor decides otherwise, Haloperidol injection will be stopped gradually. Stopping treatment suddenly may cause effects such as:

- Nausea and vomiting
- Difficulty sleeping.

Always follow your doctor's instructions carefully.

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

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 heart beat
- Extra heart beats.

Heart problems are uncommon in people taking Haloperidol injection (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. It is rare in people using Haloperidol injection (may affect up to 1 in 1,000 people).

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 Haloperidol injection (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).

An allergic reaction is uncommon in people using Haloperidol injection (may affect up to 1 in 100 people).

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.

Very common (may affect more than 1 in 10 people)

- Feeling agitated
- Difficulty in sleeping
- Headache.

Common (may affect up to 1 in 10 people)

- 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)
- Depression
- Abnormal muscle tension
- Feeling dizzy, including upon sitting up or standing up
- Feeling sleepy
- Upward movement of the eyes or fast eye movements that you cannot control

- Problems with vision, such as blurred vision
- Low blood pressure
- Nausea, vomiting
- Constipation
- Dry mouth or increased saliva
- Skin rash
- Being unable to pass urine or empty the bladder completely
- Difficulty getting and keeping an erection (impotence)
- Weight gain or loss
- Changes that show up in blood tests of the liver.

Uncommon (may affect up to 1 in 100 people)

- Effects on blood cells – low number of all types of blood cells, including severe decrease in white blood cells and low number of ‘platelets’ (cells that help blood to clot)
- Feeling confused
- Loss of sex drive or decreased sex drive
- Fits (seizures)
- Stiff muscles and joints
- Muscle spasms, twitching or contractions that you cannot control, including a spasm in the neck causing the head to twist to one side
- Problems walking
- Being short of breath
- Inflamed liver, or liver problem that causes yellowing of the skin or eyes (jaundice)
- Increased sensitivity of the skin to sunlight
- Itching
- Excessive sweating
- Changes in menstrual cycle (periods), such as no periods, or long, heavy, painful periods
- Unexpected production of breast milk
- Breast pain or discomfort
- High body temperature
- Swelling caused by fluid buildup in the body.

Rare (may affect up to 1 in 1,000 people)

- High level of the hormone ‘prolactin’ in the blood
- Narrowed airways in the lungs, causing difficulty breathing
- Difficulty or being unable to open the mouth
- Problems having sex.

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

- High level of ‘antidiuretic hormone’ in the blood (syndrome of inappropriate antidiuretic hormone secretion)
- Low level of sugar in the blood
- Swelling around the voice box or brief spasm of the vocal cords, which may cause difficulty speaking or breathing
- Sudden liver failure
- Decreased bile flow in the bile duct

- Flaking or peeling skin
- Inflamed small blood vessels, leading to a skin rash with small red or purple bumps
- Breakdown of muscle tissue (rhabdomyolysis)
- Persistent and painful erection of the penis
- Enlarged breasts in men
- Low body temperature.

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 HPR

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 Haloperidol Injection

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

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

Do not store above 25°C.

Store in the original package in order to protect from light.

Do not use this medicine if the solution is cloudy, discoloured or if there are any particles present, it should be returned unused to the pharmacist.

If only part used, discard the remaining solution.

This product should be used immediately after opening.

For single use only.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What Haloperidol Injection contains

- The active substance is Haloperidol. Each 1ml ampoule contains 5mg of haloperidol.
- The other ingredients are lactic acid and sodium hydroxide in water for injections.

What Haloperidol Injection looks like and contents of the pack

Haloperidol Injection is a clear, colourless, sterile solution for injection.

It is available in pack size of 10 x 1ml clear glass ampoules.

Marketing Authorisation Holder

Mercury Pharmaceuticals (Ireland) Ltd
4045, Kingswood Road, City West Business Park, Co Dublin, Ireland

Manufacturer

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