**Package leaflet: Information for the patient**

**HALDOL® 2 mg/ml oral solution**

haloperidol

Haldol is a registered trademark

**Read all of this leaflet carefully before you start taking 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 pharmacist.
- 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 or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

**What is in this leaflet**


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

The name of your medicine is Haldol.

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

Haldol is used in adults, adolescents and children 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.

In adolescents and children, Haldol is used to treat schizophrenia in patients aged 13 to 17 years, and to treat behavioural problems in patients aged 6 to 17 years.

Haldol is also used:
- In adolescents and children aged 10 to 17 years and in adults for movements or sounds you can’t control (tics), for example in severe Tourette’s syndrome
- In adults to help control movements in Huntington’s disease.

Haldol is sometimes used when other medicines or treatments have not worked or caused unacceptable side effects.

## 2. What you need to know before you take Haldol

**Do not take Haldol 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 Haldol – Do not take Haldol if you are taking certain medicines for'.

Do not take this medicine if any of the above applies to you. If you are not sure, talk to your doctor or pharmacist before taking Haldol.

**Warnings and precautions**

**Serious side effects**
Haldol 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 taking Haldol 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 or pharmacist before taking Haldol if you are elderly, particularly if you have dementia.

**Talk to your doctor or pharmacist 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 Haldol you take may have to be altered.

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

**Medical check ups**
Your doctor may want to take an electrocardiogram (ECG) before or during your treatment with Haldol. 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.

**Children below 6 years of age**
Haldol should not be used in children below 6 years of age. This is because it has not been studied adequately in this age group.

**Other medicines and Haldol**
Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

**Do not take Haldol 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 Haldol (see 'Do not take Haldol if').

**Special monitoring may be needed if you are taking lithium and Haldol 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 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 if you are taking any of these medicines.

**Haldol 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 before taking Haldol if you are taking any of these medicines.

**Haldol and alcohol**
Drinking alcohol while you are taking Haldol 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 taking Haldol, 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 take Haldol while you are pregnant.

The following problems may occur in newborn babies of mothers that take 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.

The exact frequency of these problems is unknown. If you took Haldol 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 taking Haldol.

**Fertility –** Haldol 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 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 taking it or after a high dose. Do not drive or use any tools or machines without discussing this with your doctor first.

**Haldol oral solution contains methyl parahydroxybenzoate**
Methyl parahydroxybenzoate may cause allergic reactions (possibly delayed).

## 3. How to take Haldol

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

**How much should you take**
Your doctor will tell you how much Haldol to take and for how long. Your doctor will also tell you whether to take Haldol one or more times a day. 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. It is very important you take the correct amount.

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 dose will normally be between 0.5 mg and 10 mg each day.
- Your doctor may adjust this to find the dose that suits you best.
- The highest dose adults should take depends on the condition you are being treated for and varies between 5 mg and 20 mg each day.

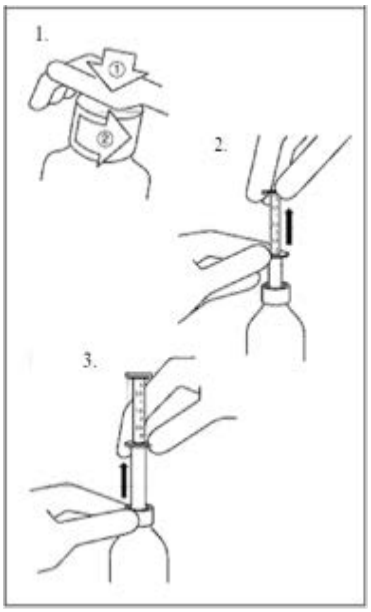
**Elderly people**
- Elderly people will normally start on 0.5 mg each day or half the lowest adult dose.
- The amount of Haldol you take will then be adjusted until the doctor finds the dose that suits you best.
- The highest dose elderly people should take is 5 mg each day unless your doctor decides a higher dose is needed.

**Children and adolescents 6 to 17 years of age**
- Your dose will normally be between 0.5 mg and 3 mg each day.
- Adolescents up to 17 years of age being treated for schizophrenia or behavioural problems may have a higher dose, up to 5 mg each day.

**Taking Haldol**
- Haldol is for oral use.
- You can mix Haldol oral solution in some water before you take it, but don’t mix it with any other liquids.

You must take the solution using the oral syringe.

- Place the bottle on a flat surface.
- Remove the cap from the bottle by pushing down on the cap while turning it anti-clockwise (figure 1).
- One end of the oral syringe has a plunger. Place the other end into the solution in the bottle.
- While holding the lower ring on the oral syringe, pull the top ring of the plunger upwards. Do this, until the mark that matches the number of millilitres (ml) or milligrams (mg) is just visible (figure 2).
- Holding the lower ring, remove the whole oral syringe from the bottle (figure 3).
- Empty the contents of the oral syringe onto a spoon or into a cup. Do this by sliding the upper ring down while still holding the lower ring.
- Drink the solution straight away.
- Close the bottle, then rinse the oral syringe with some water.




**If you take more Haldol than you should**
If you take more Haldol than you were told to or if someone else has taken any Haldol, talk to a doctor or go to the nearest hospital casualty department straight away.

**If you forget to take Haldol**

- If you forget to take a dose, take your next dose as usual. Then keep taking your medicine as your doctor has told you.
- Do not take a double dose.

**If you stop taking Haldol**
Unless your doctor tells you otherwise, you should stop taking Haldol 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 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 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 Haldol (may affect up to 1 in 100 people). Sudden deaths have occurred in patients taking 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 taking Haldol (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 taking Haldol (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 taking Haldol (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 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 decreases 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 build up 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 or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme

at www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store. By reporting side effects you can help provide more information on the safety of this medicine.

## 5. How to store Haldol

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 bottle label or carton after EXP. The expiry date refers to the last day of that month. Once the bottle is opened, use within 3 months.

This medicine does not require any special storage conditions.

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 Haldol contains**
The active substance is haloperidol. Each ml of the oral solution contains 2 mg of haloperidol.
The other ingredients are: methyl parahydroxybenzoate (E218), lactic acid and purified water.

**What Haldol looks like and contents of the pack**
Haldol is a clear, colourless solution. It is supplied in an amber bottle with a child-resistant, tamper-evident cap, and contains 100 ml of solution. An oral syringe is provided in the pack, with graduations marked in millilitres, milligrams, or both.

**Marketing Authorisation Holder**

Janssen-Cilag Ltd,
50-100 Holmers Farm Way,
High Wycombe,
Buckinghamshire,
HP12 4EG, UK.

**Manufacturer**

Janssen Pharmaceutica NV
Turnhoutseweg 30, B-2340 Beerse
Belgium

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

| | |
|---|---|
| Austria, Belgium, Cyprus, France, Italy, Luxembourg, Netherlands, Portugal, Sweden, United Kingdom: | Haldol |
| Denmark, Finland: | Serenase |
| Germany: | Haldol-Janssen |
| Greece: | Aloperidin |

**This leaflet was last revised in December 2018.**

**For information in large print, tape, CD or Braille, telephone 0800 7318450.**

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The following information is intended for healthcare professionals only:

HALDOL oral solution in a bottle with an oral syringe is intended to be used for single doses of 0.5 mg haloperidol and above (equivalent to 0.25 ml and above).

The quantity (ml) required to achieve a given single dose using HALDOL oral solution is presented below.

**Conversion table for HALDOL oral solution (2 mg/ml)**

| **mg haloperidol** | **ml HALDOL (bottle with oral syringe)** |
|---|---|
| 0.5 mg | 0.25 ml |
| 1 mg | 0.5 ml |
| 2 mg | 1 ml |
| 5 mg | 2.5 ml |
| 10 mg | 5 ml |
| 15 mg | 7.5 ml |
| 20 mg | 10 ml |