TevaArt Ref: PID: 188302_s3 P: Haloperidol UK Tablets 0.5mg 28 V-Ensure | Version: 5 12 August 2025

UK & Ireland Artwork Department

Length: 440 mm
Width: 190 mm
Depth: -

Colours Used: Template BLACK

SKU (s): 32102495 | Perforated: No | Fonts: Neo Sans For Teva. | Smallest Font Size: 9 pt (excluding codes)

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Package leaflet: Information for the patient

Haloperidol
0.5 mg Tablets

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 Haloperidol is and what it is used for**
2. **What you need to know before you take Haloperidol**
3. **How to take Haloperidol**
4. **Possible side effects**
5. **How to store Haloperidol**
6. **Contents of the pack and other information**

1. What Haloperidol is and what it is used for

Haloperidol belongs to a group of medicines called 'antipsychotics'.

Haloperidol 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, Haloperidol is used to treat schizophrenia in patients aged 13 to 17 years, and to treat behavioural problems in patients aged 6 to 17 years.

Haloperidol 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.

Haloperidol 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 Haloperidol

Do not take Haloperidol 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 take Haloperidol 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 Haloperidol.

Warnings and precautions
Serious side effects
Haloperidol 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 Haloperidol 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 Haloperidol 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 Haloperidol 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 Haloperidol.

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

Children below 6 years of age
Haloperidol 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 Haloperidol
Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

Do not take Haloperidol 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 (see 'Do not take Haloperidol if').

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

Haloperidol 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 Haloperidol if you are taking any of these medicines.

Haloperidol and alcohol
Drinking alcohol while you are taking Haloperidol 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 Haloperidol, 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 Haloperidol while you are pregnant.

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

Fertility – Haloperidol 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 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.

Haloperidol 0.5 mg contain lactose
If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.

. **Haloperidol 0.5 mg contain sodium**
This medicine contains less than 1 mmol sodium (23 mg) per tablet that is to say essentially 'sodium-free'.

3. How to take Haloperidol

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 many tablets to take and for how long. Your doctor will also tell you whether to take Haloperidol 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 number of tablets 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 Haloperidol
- Haloperidol is for oral use.
- Swallow the tablets with some water.

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

If you forget to take Haloperidol
- 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 Haloperidol
Unless your doctor tells you otherwise, you should stop taking Haloperidol 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 Haloperidol (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 Haloperidol (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 Haloperidol (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 Haloperidol (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, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme, Website: **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 Haloperidol

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 blister or carton. The expiry date refers to the last day of that month.

Store in the original container in order to protect from moisture.

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 tablets contain:
- The active substance is haloperidol.
- The other ingredients are lactose monohydrate, cellulose microcrystalline, hypromellose, sodium starch glycolate, magnesium stearate (E572), and silica, colloidal anhydrous.

What Haloperidol tablets look like and contents of the pack:
- White to off white, round shaped flat faced bevelled edge uncoated tablets scored on one side and debossed with '298' on other side. The break line is only to facilitate breaking for ease of swallowing and not to divide into equal doses.
- The product is available in pack sizes of 28, 30,42, 56, 60, 84, 90, 100 and 112 tablets.
  Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer
Marketing Authorisation holder:
Teva UK Limited, Ridings Point, Whistler Drive, Castleford, WF10 5HX, United Kingdom.

Manufacturer: PNR Pharma Consulting Ltd, Units 5 and 6, Lime Avenue, Ebbw Vale, NP23 6GL, United Kingdom.

This leaflet was last revised: August 2025
PL 00289/2578

Other sources of information
To request a copy of this leaflet in braille, large print or audio please contact:
Email: medinfo@tevauk.com,
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Please provide the following information:
Product name: Haloperidol 0.5 mg Tablets
Reference: PL 00289/2578

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