

Haloperidol 2 mg/ml, oral solution

Haloperidol is sometimes used when other medications or treatments have not worked or have caused unacceptable side effects.

What is Haloperidol and what is it used for?

The name of the medication is Haldol. Haloperidol contains the active ingredient haloperidol, which belongs to a group of medicines called "antipsychotics."

Haloperidol is used in adults, adolescents, and children for conditions that affect how you think, feel, or behave. Examples include mental health problems (such as schizophrenia and bipolar disorder) and behavioral problems.

These conditions can cause you to: Feel confused (delirium), See, hear, feel, or smell things that aren't there (hallucinations), Believe things that aren't true (delusions), Be unusually suspicious (paranoia), Be very excited, agitated, enthusiastic, impulsive, or hyperactive, Feel very aggressive, hostile, or violent.

In adolescents and children, Haloperidol is used in patients aged 13 to 17 for the treatment of schizophrenia and in patients aged 6 to 17 for the treatment of behavioral problems.

Haloperidol is also used:

- In adolescents and children aged 10 to 17 and in adults for movements or sounds they make without control (tics), for example in a severe form of Gilles de la Tourette syndrome.
- In adults as a means to control movements in Huntington's disease.

Haloperidol is sometimes used when other medications or treatments have not worked or have caused unacceptable side effects.

When should you not take this medicine or be extra careful with it?

When should you not take this medicine?

- You are allergic to any of the substances in this medicine. ,You are less aware of your surroundings or your reactions become unusually slow., You have Parkinson's disease., You have a form of dementia called "Lewy body dementia.", You have progressive supranuclear palsy (PSP),,You have a heart condition called "prolonged QT interval" or another problem with your heart rhythm that is visible as an abnormal recording on an electrocardiogram (ECG),,You have heart failure or have recently had a heart attack., You have a low level of potassium in your blood that has not been treated., You are taking any of the medications listed under "Are you taking any other medications?" - Do not use Haloperidol if you are taking certain medications."

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

When should you be extra careful with this medicine?

Serious side effects: Haloperidol can cause heart problems, problems with controlling movements of the body or limbs, and a serious side effect called "neuroleptic malignant syndrome." It can also cause serious allergic reactions and blood clots. You should be aware of serious side effects while taking Haloperidol because you may need urgent medical treatment. See "Watch for serious side effects" in section 4.

Elderly and people with dementia: A small increase in the number of cases of death and stroke has been reported in elderly people with dementia who use drugs for psychotic symptoms. Contact your doctor or pharmacist before taking Haloperidol if you are elderly, especially if you have dementia.

Contact your doctor or pharmacist if you have any of the following:

- A slow heartbeat, heart disease, or if a close family member has suddenly died from heart problems. Low blood pressure, dizziness when standing up or getting up. Low potassium or magnesium levels (or of another "electrolyte") in your blood. Your doctor decides how this is treated. You have ever had a bleeding in your brain or your doctor has told you that you have a greater chance than others of having a stroke. Epilepsy or you have ever had seizures (convulsions). Problems with your kidneys, liver, or thyroid. A high level of the hormone "prolactin" in your blood, or cancer that may have been caused by a high prolactin level (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 you are starting to feel depressed.

You may need to be monitored more closely and the amount of Haloperidol you take may need to be adjusted.

If you are unsure if any of the above applies to you, talk to your doctor or pharmacist before taking Haldol.

Medical Checks: Your doctor may want to make 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 potassium or magnesium levels (or another "electrolyte") in your blood before or during your treatment with Haldol.

Children under 6 years: Haloperidol should not be used in children under 6 years of age. The reason for this is that it has not been sufficiently studied in this age group.

Are you taking other medicines?

If you are taking other medicines besides Haldol, have done so recently, or may take other medicines in the near future, tell your doctor or pharmacist.

Do not use Haloperidol if you are taking certain medicines for:

- Problems with your heart rate (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, thioridazine, 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 painkiller or for the treatment of drug addiction). These medicines can increase the risk of heart problems. So tell your doctor if you are taking any of these and do not use Haloperidol.

Special monitoring may be necessary if you are taking both lithium and Haldol. Tell your doctor immediately and stop taking both medicines if you experience:

- Unexplained fever or movements you cannot control
- Confusion, disorientation, headache, balance problems, and drowsiness.

These are signs of a serious condition.

Certain medicines can affect the effectiveness of Haloperidol or increase the risk of heart problems. Tell your doctor if you are taking any of the following medicines:

- 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 quit smoking)
- Carbamazepine, phenobarbital, or phenytoin (for epilepsy)
- Rifampicin (for bacterial infections)
- Itraconazole, posaconazole, or voriconazole (for fungal infections)
- Ketoconazole tablets (for treatment of 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 other medicines to lower blood pressure, such as diuretics (water pills).

Your doctor may need to adjust your dose of Haloperidol if you take any of these medicines.

Haloperidol may affect the effectiveness of the following types of medicines:

Tell your doctor if you are taking medicines:

- To calm you down or help you sleep (sedatives)
- For pain relief (strong painkillers)
- For depression (tricyclic antidepressants)
- To lower blood pressure (such as guanethidine and methyldopa)
- For severe allergic reactions (adrenaline)
- For attention deficit hyperactivity disorder (ADHD) or narcolepsy (known as 'stimulants')
- For Parkinson's disease (such as levodopa)
- To thin the blood (phenindione).

If you are taking any of these medicines, talk to your doctor before taking Haldol.

What to be aware of with alcohol?

If you drink alcohol while taking Haldol, you may feel drowsy and less alert. This means that you should be careful about how much alcohol you drink. Discuss the use of alcohol while taking Haloperidol with your doctor and let your doctor know how much you drink.

Pregnancy, breastfeeding, and fertility

Pregnancy – Are you pregnant, think you might be pregnant, or want to become pregnant? Then contact your doctor before using this medicine. Your doctor may advise you not to use Haloperidol if you are pregnant. In newborn babies of mothers who use Haloperidol in the last 3 months of their pregnancy (the last trimester), the following problems may occur:

- Muscle tremors, stiff or weak muscles
- Drowsiness or agitation

- Breathing or feeding problems.

The exact frequency of these problems is not known. If you have used Haloperidol during your pregnancy and your baby develops any of these side effects, contact your doctor. Breastfeeding – Consult your doctor if you are breastfeeding or planning to breastfeed.

The reason for this is that small amounts of the medicine can pass into breast milk and therefore into the baby. Your doctor will discuss the risks and benefits of breastfeeding during the use of Haloperidol with you.

Fertility – Haloperidol can increase the level of the hormone 'prolactin', which can affect the fertility of men and women. Talk to your doctor if you have any questions about this.

Driving and using machines

Haloperidol can affect your driving ability and your ability to use machinery. Due to side effects such as drowsiness, you may be less alert, especially at the beginning of use or after a high dose. Do not drive or use tools or machines without consulting your doctor first.

Haloperidol syrup contains methylparahydroxybenzoate (E218) Methylparahydroxybenzoate can cause allergic reactions (possibly delayed).

How do you take this medication?

Always take this medicine exactly as your doctor or pharmacist has told you. If you are unsure about the correct use, contact your doctor or pharmacist.

How much should you take?

Your doctor will determine how much Haloperidol you should take and for how long. Your doctor will also tell you whether to take Haloperidol once or multiple times a day. It may take a while before you feel the full effect of the medicine. Usually, the doctor will prescribe a low dose to start with and then adjust it according to your needs. It is very important to take the correct dose.

Your haloperidol dose depends on: Your age, The condition for which you are being treated, Whether you have kidney or liver problems, Other medications you are taking.

Adults: Your dose is normally between 0.5 mg and 10 mg per day. Your doctor may adjust this to find the dose that suits you best. The maximum dose for adults depends on the condition being treated and ranges from 5 mg to 20 mg per day.

Elderly: The elderly normally start with 0.5 mg per day or half the lowest dose for adults. The amount of Haloperidol you take is then adjusted until the doctor finds the dose that suits you best. ☐ The maximum dose for the elderly is 5 mg per day, unless your doctor decides that a higher dose is necessary.

Children and adolescents aged 6 to 17 years: Your dose is normally between 0.5 mg and 3 mg per day. Adolescents aged 17 or younger who are being treated for schizophrenia or behavioral problems may be given a higher dose of up to 5 mg per day.

How do you take this medication?

- Haloperidol is for oral use.
- You can mix Haloperidol liquid with some water before taking it, but do not mix it with other liquids.
- Remove the cap from the bottle by pressing the cap down and turning it counterclockwise at the same time.
- Hold the bottle upside down over a spoon.
- Gently squeeze the sides of the bottle and count the number of drops you need to take.
- Drink the mixture right away.
- Close the bottle.

Have you taken too much of this medication?

If you have taken too much of Haloperidol or if someone else has taken Haldol, immediately contact your doctor or go to the Emergency Department of the nearest hospital.

Did you forget to take this medicine?

If you missed a dose, take the next dose according to the normal schedule. Continue to take the medicine as prescribed. Do not take a double dose to make up for a missed dose.

If you stop taking this medicine: Unless your doctor instructs otherwise, you should gradually stop taking Haldol. Suddenly stopping the treatment can cause the following side effects, for example: Nausea and vomiting, Sleep problems. Always follow your doctor's instructions exactly.

Do you have any other questions about using this medication?: contact your doctor or pharmacist.

Possible side effects

Like any medication, this medication can have side effects, although not everyone experiences them. Pay attention to serious side effects Tell your doctor immediately if you notice or suspect any of the following problems. You may need urgent medical treatment.

Heart problems: Abnormal heart rhythm - this means that the heart no longer works normally and you may lose consciousness, Abnormally fast heartbeat, Extra heartbeats.

Heart problems sometimes occur in people who use Haloperidol (can occur in up to 1 in 100 people). Sudden death has occurred in patients taking this medication, but the exact frequency of these deaths is unknown. Cardiac arrest (the heart stops beating) has also occurred in people taking antipsychotic drugs.

A serious problem called 'neuroleptic malignant syndrome'. This causes high fever, severe muscle stiffness, confusion, and loss of consciousness. It rarely occurs in people who use Haloperidol (can occur in 1 in 1,000 people).

Problems controlling body or limb movements (extrapyramidal disorder), such as: Movements of the mouth, tongue, jaw, and sometimes the limbs (tardive dyskinesia), Restlessness or difficulty staying still, more body movements, Slow body movements or reduction of body movements, pulling or twisting movements, Tremors or muscle stiffness, shuffling gait, Inability to move, No normal facial expression, the face sometimes looks like a mask.

These symptoms are very common in people who use Haloperidol (can occur in more than 1 in 10 people). If you experience any of these effects, you may be given an additional medication.

Severe allergic reaction, including the following symptoms: Swollen face, lips, mouth, tongue or throat, Swallowing or breathing difficulties, Itchy skin rash (hives).

An allergic reaction sometimes occurs in people using Haloperidol (can occur in 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 drugs. Signs of DVT in the leg include swelling, pain, and redness, but the clot can also move to the lungs and cause chest pain and breathing problems. Blood clots can be very serious, so tell your doctor immediately if you notice any of these problems.

Tell your doctor immediately if you notice any of the serious side effects listed above.

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

Very common (may occur in more than 1 in 10 people): Restlessness, Sleep problems, Headache

Common (may occur in 1 in 10 people): Severe 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, Dizziness, for example, when sitting or standing up, Drowsiness, Upward movement of the eyes or rapid eye movements that you cannot control, Vision problems, such as blurred vision, Low blood pressure, Nausea, vomiting, Constipation, Dry mouth or increased saliva production, Skin rash, Inability to urinate or inability to completely empty the bladder, Difficulty getting and maintaining an erection (impotence), Weight gain or weight loss, Changes revealed by blood tests to determine liver function.

Sometimes (may occur in 1 in 100 people): Effects on blood cells - low numbers of all types of blood cells, including significant decreases in the number of white blood cells and a low number of "platelets" (cells that help the blood clot), Feeling confused, No or decreased sexual desire.

How to store this medicine?

Keep out of sight and reach of children.

Do not use this medicine after the expiry date which is stated on the label or box after EXP. There is a month and a year mentioned. The last day of that month is the expiry date. Once the bottle has been opened, the contents are still good for 3 months.

There are no special storage conditions for this medicine.