

Haloperidol 200micrograms/ml Oral Solution

Read all of this leaflet carefully before you start taking or giving this medicine to a child to whom it has been prescribed because it contains important information for you and your child.

- ▶ 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 or your child 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 or your child get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

The name of your medicine is Haloperidol 200micrograms/ml Oral Solution but it will be referred to as 'Haloperidol ' throughout this leaflet.

What is in this leaflet:

- 1. What Haloperidol is and what it is used for**
- 2. What you need to know before you take or give Haloperidol**
- 3. How to take or give 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

This medicine contains the active substance haloperidol. This belongs to a group of medicines called 'antipsychotics'.

Haloperidol is used in 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 or your child:

- ▶ 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 for movements or sounds you can't control (tics), for example in severe Tourette's syndrome.

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

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Marketing Authorisation Holder and Manufacturer:

SyriMed,
Unit 4, Bradfield Road,
Ruislip, Middlesex,
HA4 0NU, UK.

If this leaflet is hard to see or read, please call +44 (0) 208 515 3700 for help.

This leaflet was last revised in 04/2025.

- ▶ 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 or your child gets 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 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 carton and label after 'EXP'. The expiry date refers to the last day of that month.
- ▶ Do not store above 25°C.
- ▶ Discard 30 days after first opening.
- ▶ Do not use this medicine if you notice that the solution becomes discoloured or shows any signs of deterioration. Seek the advice of your pharmacist.
- ▶ 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 contains

The active substance is haloperidol. Each ml of oral solution contains 200micrograms haloperidol.

The other ingredients are (S)-lactic acid, methyl parahydroxybenzoate (E218) and purified water.

What Haloperidol looks like and contents of the pack

Haloperidol is a clear, colourless oral solution supplied in amber glass bottles with a tamper evident child resistant plastic cap. The pack also contains 10ml oral syringe with 0.25ml graduation marks and a syringe adaptor.

Haloperidol Oral Solution is supplied in bottles containing 100ml and 200ml of oral solution.

Not all pack sizes may be marketed.

- ▶ 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



Conversion table for Haloperidol 200micrograms/ml Oral Solution

Dose in milligrams (mg) of haloperidol	Volume in millilitres (ml) of Haloperidol 200micrograms/ml (0.2mg/ml) to be given using dosing syringe
0.1mg	0.5ml
0.2mg	1.0ml
0.25mg	1.25ml
0.3mg	1.5ml
0.4mg	2.0ml
0.5mg	2.5ml
1mg	5ml
2mg	10ml

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2. What you need to know before you take or give Haloperidol

Do not take or give Haloperidol if you or your child:

- ▶ 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 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 or give this medicine if any of the above applies to you or your child. If you are not sure, talk to your doctor or pharmacist before taking or giving 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 or giving Haloperidol because you or your child 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 or your child 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 have bipolar disorder and start to feel depressed.

You or your child may need to be more closely monitored, and the amount of Haloperidol you or your child take may have to be altered.

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

Medical check ups

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

Blood tests

Your doctor may want to check the levels of potassium or magnesium (or other 'electrolyte') in your or your child's 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 or your child are taking, have recently taken or might take any other medicines. This includes medicines that you buy without a prescription or herbal medicines.

Do not take or give Haloperidol if you are taking or giving certain medicines for:

- ▶ Problems with your or your child's 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 or your child 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 or your child are taking any of these and do not take or give Haloperidol (see 'Do not take Haloperidol if').

Special monitoring may be needed if you or your child are taking lithium and Haloperidol at the same time.

Tell your doctor straight away and stop taking or giving both medicines if you or your child gets:

- ▶ Fever that cannot be explained or movements you or your child 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 or your child 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 or your child are taking any other medicines to lower blood pressure, such as water tablets (diuretics).

Your doctor may have to change you or your child's dose of Haloperidol if you are taking or giving any of these medicines.

Haloperidol can affect the way the following types of medicine work

Tell your doctor if you or your child are taking medicines for:

- ▶ Calming you or your child down or helping you or your child to sleep (tranquillisers)
- ▶ Pain (strong pain killers)
- ▶ Depression ('tricyclic antidepressants')
- ▶ Lowering blood pressure (such as guanethidine and methyl dopa)
- ▶ 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 or giving Haloperidol if you or your child are taking any of these medicines.

Haloperidol with 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 before taking this medicine. Your doctor may advise you or your child 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 or your child 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 or your child's 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 contains:

Methyl parahydroxybenzoate (E218): May cause an allergic reaction (possibly delayed).

3. How to take or give Haloperidol

Always take or give this medicine exactly as your doctor or pharmacist has told you. You should check with your doctor or pharmacist if you are not sure.

How much should you take or give

Your doctor will tell you how much Haloperidol to take or give and for how long. Your doctor will also tell you whether to take or give Haloperidol one or more times a day. It may be some time before you or your child feel the full effect of the medicine. Your doctor will normally give you or your child a low dose to start, and then adjust the dose to suit you or your child. It is very important you take or give the correct amount.

Your or your child's dose of Haloperidol will depend on:

- ▶ Age
- ▶ What condition you or your child are being treated for
- ▶ Whether you or your child have problems with the kidneys or liver
- ▶ Other medicines you or your child are taking.

Children and adolescents 6 to 17 years of age

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

Taking or giving Haloperidol

- ▶ This medicine is for oral use
- ▶ You can mix Haloperidol oral solution in some water before you take it, but don't mix it with any other liquids.

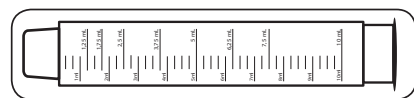
Method of administration:

This medicinal product must be taken orally.

Use the measuring syringe provided in the pack to deliver the required dose.

Your doctor, pharmacist or nurse will show you how to administer this medicine. The box containing this medicine will contain a 10ml dosing syringe and a syringe adaptor.

Diagram of 10ml syringe

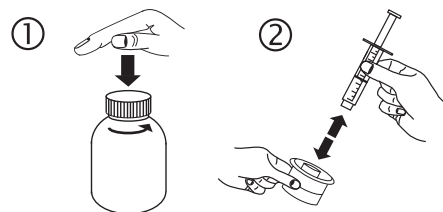


On the 10ml syringe, each small graduation mark equals 0.25ml the equivalent of 50micrograms. Graduations are numbered in increments of 1ml. Each 1ml provides 200microgram (same as 0.2mg) of Haloperidol.

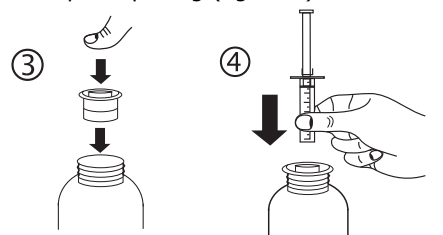
If you are not sure how to use the syringe ask your pharmacist for help.

Instructions for the use of syringe:

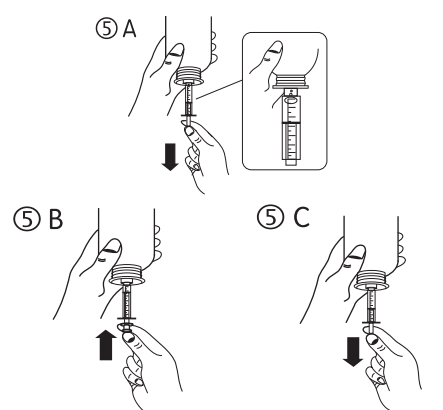
- a) Open the bottle: press the cap and turn it anticlockwise (figure 1). Separate the adaptor from the syringe (figure 2).



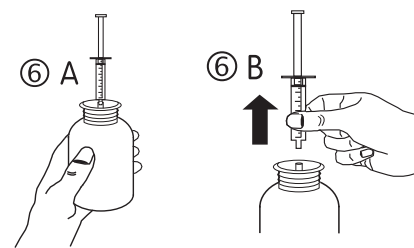
- b) Insert the adaptor into the bottle neck (figure 3). Ensure it is properly fixed. Take the syringe and put it in the adaptor opening (figure 4).



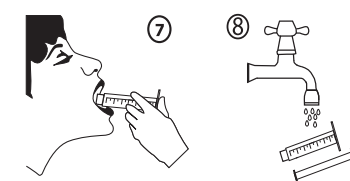
- c) Turn the bottle upside down. Fill the syringe with a small amount of solution by pulling the piston down (figure 5A), then push the piston upwards in order to remove any possible bubble (figure 5B). Pull the piston down to the graduation mark corresponding to the quantity in millilitres (ml) prescribed by your doctor (figure 5C).



- d) Turn the bottle the right way up (figure 6A). Remove the syringe from the adaptor (figure 6B).



- e) During administration the oral syringe should be directed towards the cheek on the side of the mouth. Empty the content of the syringe by pushing the piston to the bottom of the syringe (figure 7). The contents of the syringe should be emptied into the side cheek of the patient's mouth to avoid a choking hazard. Close the bottle with the plastic screw cap. Wash the syringe with water (figure 8).



If you are still not sure how to administer the medicine, please ask your pharmacist.

If you take or give more Haloperidol than you should

If you or your child takes 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 or give Haloperidol

- ▶ If you or your child forget to take a dose, take or give the next dose as usual. Then keep taking or giving your or your child's medicine as your doctor has told you
- ▶ Do not take or give a double dose to make up for a forgotten dose.

If you stop taking or giving Haloperidol

Unless your doctor tells you otherwise, you or your child 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 or your child notice or suspect any of the following. You or your child 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 or your child gets any of these effects, you or your child 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 or your child notices any of these problems.

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

Other side effects

Tell your doctor if you or your child notices or suspects 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

The following information is intended for healthcare professionals only:

Haloperidol 200micrograms/ml Oral Solution is supplied with a 10ml oral syringe and is intended to be used for single doses of 0.1mg Haloperidol and above (equivalent to 0.5ml and above). Doses greater than 2mg (equivalent to 10ml oral solution) should be administered using a 1mg/ml Oral Solution.

The quantity (ml) required to achieve a given single dose using Haloperidol 200micrograms/ml Oral Solution is presented overleaf.

Package leaflet: Information for the user
Halkid® 200micrograms/ml Oral Solution

haloperidol

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 or your child gets 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 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 Halkid

- ▶ 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 carton and label after 'EXP'. The expiry date refers to the last day of that month.
- ▶ Do not store above 25°C.
- ▶ Discard 30 days after first opening.
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6. Contents of the pack and other information

What Halkid contains

The active substance is haloperidol. Each ml of oral solution contains 200micrograms haloperidol.

The other ingredients are (S)-lactic acid, methyl parahydroxybenzoate (E218) and purified water.

What Halkid looks like and contents of the pack

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Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer:

SyriMed,
Unit 4, Bradfield Road,
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HA4 0NU, UK.

If this leaflet is hard to see or read, please call +44 (0) 208 515 3700 for help.

This medicine is authorised in the Member States of the European Economic Area and in the United Kingdom (Northern Ireland) under the following names:

Malta, United Kingdom (Northern Ireland):
Halkid® 200micrograms/ml Oral Solution

This leaflet was last revised in 07/2022. Halkid® is a registered trademark of Thame Laboratories.

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These illnesses may make you or your child:

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- ▶ 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, Halkid is used to treat schizophrenia in patients aged 13 to 17 years, and to treat behavioural problems in patients aged 6 to 17 years:

Halkid is also used in adolescents and children aged 10 to 17 years for movements or sounds you can't control (tics), for example in severe Tourette's syndrome.

Halkid 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 or give Halkid

Do not take or give Halkid if you or your child:

- ▶ You are allergic to Halkid or any of the other ingredients of this medicine (listed in section 6)
- ▶ You are less aware of things around you or 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 Halkid - Do not take Halkid if you are taking certain medicines for'.

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

Warnings and precautions

Serious side effects

Halkid 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 or giving Halkid because you or your child 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 Halkid if you are elderly, particularly if you have dementia.

Talk to your doctor or pharmacist if you or your child 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 have bipolar disorder and start to feel depressed.

You or your child may need to be more closely monitored, and the amount of Halkid you or your child take may have to be altered.

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

Medical check ups

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

Blood tests

Your doctor may want to check the levels of potassium or magnesium (or other 'electrolyte') in your or your child's blood before or during your treatment with Halkid.

Children below 6 years of age

Halkid 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 Halkid

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

Do not take or give Halkid if you are taking or giving certain medicines for:

- ▶ Problems with your or your child's 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 or your child 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 or your child are taking any of these and do not take or give Halkid (see 'Do not take Halkid if').



Conversion table for Halkid 200micrograms/ml Oral Solution

Dose in milligrams (mg) of haloperidol	Volume in millilitres (ml) of Halkid 200micrograms/ml (0.2mg/ml) to be given using dosing syringe
0.1mg	0.5ml
0.2mg	1.0ml
0.25mg	1.25ml
0.3mg	1.5ml
0.4mg	2.0ml
0.5mg	2.5ml
1mg	5ml
2mg	10ml

Special monitoring may be needed if you or your child are taking lithium and Halkid at the same time.

Tell your doctor straight away and stop taking or giving both medicines if you or your child gets:

- ▶ Fever that cannot be explained or movements you or your child 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 Halkid works or may make heart problems more likely

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

Your doctor may have to change your or your child's dose of Halkid if you are taking or giving any of these medicines.

Halkid can affect the way the following types of medicine work

Tell your doctor if you or your child are taking medicines for:

- ▶ Calming you or your child down or helping you or your child 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 or giving Halkid if you or your child are taking any of these medicines.

Halkid and alcohol

Drinking alcohol while you are taking Halkid 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 Halkid 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 before taking this medicine. Your doctor may advise you or your child not to take Halkid while you are pregnant.

The following problems may occur in newborn babies of mothers that take Halkid 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 Halkid while pregnant and your baby develops any of these side effects, contact your doctor.

Breast-feeding

Talk to your doctor if you or your child 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 Halkid.

Fertility

Halkid 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

Halkid can affect your or your child's 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.

Halkid contains:

Methyl parahydroxybenzoate (E218): May cause an allergic reaction (possibly delayed).

3. How to take or give Halkid

Always take or give this medicine exactly as your doctor or pharmacist has told you. You should check with your doctor or pharmacist if you are not sure.

How much should you take or give

Your doctor will tell you how much Halkid to take or give and for how long. Your doctor will also tell you whether to take or give Halkid one or more times a day. It may be some time before you or your child feel the full effect of the medicine. Your doctor will normally give you or your child a low dose to start, and then adjust the dose to suit you or your child. It is very important you take or give the correct amount.

Your or your child's dose of Haloperidol will depend on:

- ▶ Age
- ▶ What condition you or your child are being treated for
- ▶ Whether you or your child have problems with the kidneys or liver
- ▶ Other medicines you or your child are taking.

Children and adolescents 6 to 17 years of age

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

Taking or giving Halkid

- ▶ This medicine is for oral use
- ▶ You can mix Halkid oral solution in some water before you take it, but don't mix it with any other liquids.

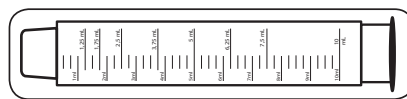
Method of administration:

This medicinal product must be taken orally.

Use the measuring syringe provided in the pack to deliver the required dose.

Your doctor, pharmacist or nurse will show you how to administer this medicine. The box containing this medicine will contain a 10ml dosing syringe and a syringe adaptor.

Diagram of 10ml syringe

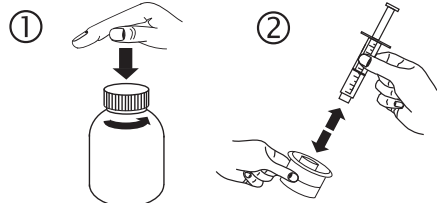


On the 10ml syringe, each small graduation mark equals 0.25ml the equivalent of 50micrograms. Graduations are numbered in increments of 1ml. Each 1ml provides 200microgram (same as 0.2mg) of Halkid.

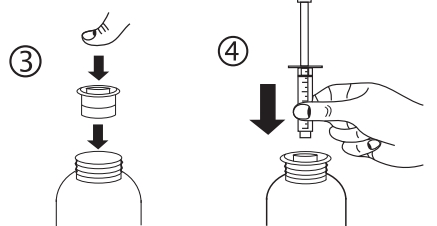
If you are not sure how to use the syringe ask your pharmacist for help.

Instructions for the use of syringe:

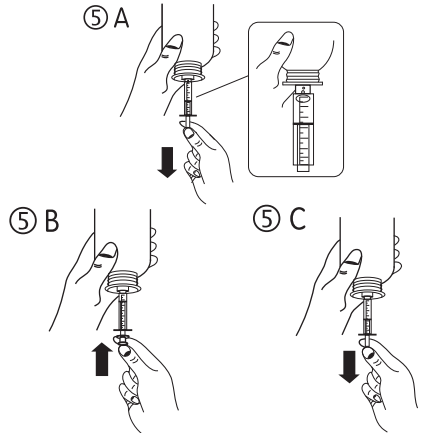
- a)** Open the bottle: press the cap and turn it anticlockwise (figure 1). Separate the adaptor from the syringe (figure 2).



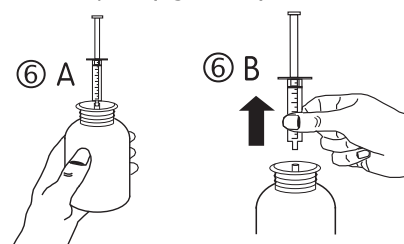
- b)** Insert the adaptor into the bottle neck (figure 3). Ensure it is properly fixed. Take the syringe and put it in the adaptor opening (figure 4).



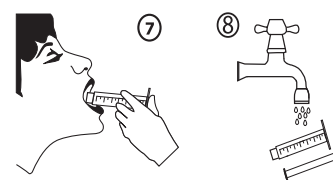
- c)** Turn the bottle upside down. Fill the syringe with a small amount of solution by pulling the piston down (figure 5A), then push the piston upwards in order to remove any possible bubble (figure 5B). Pull the piston down to the graduation mark corresponding to the quantity in millilitres (ml) prescribed by your doctor (figure 5C).



- d)** Turn the bottle the right way up (figure 6A). Remove the syringe from the adaptor (figure 6B).



- e)** During administration the oral syringe should be directed towards the cheek on the side of the mouth. Empty the content of the syringe by pushing the piston to the bottom of the syringe (figure 7). The contents of the syringe should be emptied into the side cheek of the patient's mouth to avoid a choking hazard. Close the bottle with the plastic screw cap. Wash the syringe with water (figure 8).



If you are still not sure how to administer the medicine, please ask your pharmacist.

If you take or give more Halkid than you should

If you or your child takes more Halkid than you were told to or if someone else has taken any Halkid, talk to a doctor or go to the nearest hospital casualty department straight away.

If you forget to take or give Halkid

- ▶ If you or your child forget to take a dose, take or give the next dose as usual. Then keep taking or giving your or your child's medicine as your doctor has told you
- ▶ Do not take or give a double dose to make up for a forgotten dose.

If you stop taking or giving Halkid

Unless your doctor tells you otherwise, you or your child should stop taking Halkid 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 or your child notice or suspect any of the following. You or your child 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 Halkid (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 Halkid (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 Halkid (may affect more than 1 in 10 people). If you or your child gets any of these effects, you or your child 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 Halkid (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 or your child notices any of these problems.

Tell your doctor straight away if you or your child notices any of the serious side effects above.

Other side effects

Tell your doctor if you or your child notices or suspects 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.

The following information is intended for healthcare professionals only:

Halkid 200micrograms/ml Oral Solution is supplied with a 10ml oral syringe and is intended to be used for single doses of 0.1mg Halkid and above (equivalent to 0.5ml and above). Doses greater than 2mg (equivalent to 10ml oral solution) should be administered using a 1mg/ml Oral Solution.

The quantity (ml) required to achieve a given single dose using Halkid 200micrograms/ml Oral Solution is presented overleaf.