

PATIENT PACKAGE INSERT IN ACCORDANCE WITH THE PHARMACISTS' REGULATIONS (PREPARATIONS) – 1986
The medicine is dispensed with a doctor's prescription only

HALDOL® Decanoas

Solution for intramuscular injection

Each ampoule contains 1 ml.

Each 1 ml contains:

Haloperidol 100 mg (equivalent to 141.04 mg haloperidol decanoate)

Inactive and allergenic ingredients in the preparation – see section 6 – “Further information”.

Read the leaflet carefully in its entirety before using the medicine. This leaflet contains concise information about the medicine. If you have further questions, refer to the doctor or pharmacist.

This medicine has been prescribed to treat your ailment. Do not pass it on to others. It may harm them even if it seems to you that their ailment is similar. The medicine is not intended for children.

1. WHAT IS THE MEDICINE INTENDED FOR?

Maintenance treatment in patients with schizophrenia.

Therapeutic group: Antipsychotics from the butyrophenone group.

2. BEFORE USING THE MEDICINE

Do not use the medicine if:

- You are sensitive (allergic) to the active ingredient or to any of the additional ingredients contained in the medicine.
- You are less aware of things around you or your reactions become unusually slow.
- You suffer from Parkinson's disease.
- You have 'Lewy Body' dementia.
- You have progressive supranuclear palsy (PSP).
- You have a heart disorder called prolonged QT interval, or any other problem with your heart rhythm that appears as an abnormal finding on an ECG tracing (electrocardiogram).
- You have heart failure or recently had a heart attack.
- You are suffering, or have suffered in the past, from heart rhythm disturbances or an especially slow heart rate.
- You are taking certain medicines that affect heart rate.
- You have a low level of potassium in your blood, which has not been treated.
- You suffer from an illness that affects a part of the brain called the basal ganglia.
- You are taking one of the medicines appearing on the list of medicines that should not be taken with Haldol (see "Drug interactions").

Do not use this medicine if any of the above apply to you. If you are uncertain, consult the doctor before taking the preparation.

Special warnings regarding use of the medicine

Serious side effects

Haldol Decanoas can cause problems with the heart, problems controlling body or limb movements and a serious side effect called 'neuroleptic malignant syndrome'. Haldol Decanoas 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 'Serious side effects' in section 4.

Elderly people and people with dementia

A small increase in cases of death and stroke has been reported for elderly people with dementia who are taking antipsychotic medicines.

Do not use the medicine without consulting the doctor before starting treatment:

If you are suffering, or have suffered in the past, from:

- Blood clots or if one of your relatives is suffering, or has suffered in the past, from this problem. Blood clots in the legs or lungs have occurred in patients treated with preparations to treat schizophrenia.
- Heart problems, slow heartbeat, you are taking medicines to treat heart disease, or if there is a family history of heart problems, one of your close relatives died suddenly of heart problems.
- Depression that is not being treated.
- Low blood pressure, or you feel dizzy upon sitting up or standing up.
- A low level of potassium or magnesium (or another electrolyte) in the blood. Your doctor will decide how to treat this.
- Problems with your kidneys, liver or thyroid gland.
- Epilepsy or you have ever had fits (convulsions).
- If you ever had bleeding in the brain, or your doctor has told you that you are more likely than other people to have a stroke.
- Long-standing eating problems.
- A benign adrenal gland tumor (phaeochromocytoma).
- A high level of the hormone prolactin in the blood, or cancer that may be caused by high prolactin levels (such as breast cancer).

You may need to be more closely monitored, and it may be necessary to alter the dosage of Haldol Decanoas you are taking.

If you are not sure if any of the conditions described above apply to you, consult with your doctor or pharmacist before taking Haldol Decanoas.

Tests and follow-up

Your doctor may want to refer you for an electrocardiogram test (ECG) before or during your treatment with Haldol Decanoas. The ECG test measures the electrical activity of your heart.

Blood tests

Your doctor may want to check the levels of potassium or magnesium (or another electrolyte) in your blood, before or during your treatment with Haldol Decanoas.

Children and adolescents

Do not use Haldol Decanoas in children and adolescents under 18 years of age. This is because the medicine has not been tested in this age group.

Drug interactions

If you are taking, or have recently taken, other medicines, including non-prescription medicines or nutritional supplements, tell the doctor or pharmacist.

Do not take Haldol if you are taking certain medicines to treat:

- Problems with your heart rate (such as: amiodarone, dofetilide, disopyramide, dronedarone, ibutilide, quinidine and sotalol)
- Depression (such as: citalopram or escitalopram)
- Psychoses (such as: fluphenazine, levomepromazine, perphenazine, pimozide, prochlorperazine, promazine, sertindole, thiorizadine, trifluoperazine, trifluopromazine 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 (to treat chest pain or to lower blood pressure) or methadone (to relieve pain or to treat drug addiction).

These medicines may increase the risk for heart problems; therefore, consult with the doctor if you are taking any of these medicines and do not take Haldol Decanoas (see 'Do not use the medicine if').

Special monitoring may be needed if you are taking lithium and Haldol Decanoas at the same time.

Tell your doctor straight away and stop taking both medicines if:

- you have inexplicable fever or uncontrollable movements.
- you experience confusion, disorientation, headache, balance problems and feeling sleepy.

These are signs of a serious condition.

Certain medicines may affect the way that Haldol Decanoas works or may increase the risk for heart problems.

Tell the doctor if you are taking:

- Alprazolam or buspirone (to treat anxiety)
- Duloxetine, fluoxetine, fluvoxamine, nefazodone, paroxetine, sertraline, St. John's wort (*Hypericum perforatum*) or venlafaxine (to treat depression)
- Bupropion (to treat depression or to help smoking cessation)
- Carbamazepine, phenobarbital or phenytoin (to treat epilepsy)
- Rifampicin (to treat bacterial infections)
- Itraconazole, posaconazole or voriconazole (to treat fungal infections)
- Ketoconazole tablets (to treat Cushing's syndrome)
- Indinavir, ritonavir or saquinavir (to treat human immunodeficiency virus – HIV)
- Chlorpromazine or promethazine (to treat nausea and vomiting)
- Verapamil (to treat hypertension or heart problems).

Also, inform your doctor if you are taking other medicines to lower blood pressure, such as diuretics.

Your doctor may have to change the dosage of Haldol Decanoas that you are taking 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:

- Sedation or help with sleep disorders (sedatives)
- Treating pain (strong painkillers)
- Treating depression (tricyclic antidepressants)
- Lowering blood pressure (such as guanethidine and methyl dopa)
- Treating severe allergic reactions (adrenaline)
- Treating attention deficit hyperactivity disorder (ADHD) or narcolepsy (known as stimulants)
- Treating Parkinson's disease (such as levodopa)
- Thinning the blood (phenindione).

If you are taking any of these medicines, consult with your doctor before taking Haldol Decanoas.

Use of the medicine and alcohol consumption

Drinking alcohol while taking Haldol Decanoas might make you feel sleepy and less alert. This means you should be careful about how much alcohol you drink. Consult with the doctor about drinking alcohol while taking Haldol Decanoas, and tell your doctor about the amount of alcohol you drink.

Pregnancy, breastfeeding and fertility

Pregnancy – If you are pregnant, think you are pregnant, or are planning to

become pregnant, refer to the doctor for advice. You doctor may advise you not to take Haldol Decanoas during pregnancy.

The following problems may occur in newborn babies of mothers that take Haldol Decanoas in the last 3 months of their pregnancy (the last trimester):

- Muscle tremors, stiff or weak muscles
- Sleepiness or agitation
- Breathing or feeding difficulties

The exact frequency of these problems is unknown. If you took Haldol Decanoas while pregnant and your baby develops any of these side effects, refer to a doctor.

Breastfeeding – If you are breastfeeding or planning to breastfeed, consult with the doctor. This is because small amounts of the medicine may pass into the mother's milk and on to the baby. Your doctor will discuss with you the risks and benefits of breastfeeding while you are taking Haldol Decanoas.

Fertility – Haldol may increase your levels of a hormone called prolactin, which may affect fertility in men and women. Consult with your doctor if you have any questions about this.

Driving and operating machinery

Haldol Decanoas can affect your ability to drive and use tools and machinery. Side effects, such as feeling sleepy, may affect your alertness, particularly when you first start treatment or after getting a high dose. Do not drive or use any tools or machinery without discussing this with your doctor first.

Important information regarding some of the ingredients of the medicine

This medicine contains 15 mg of benzyl alcohol in each ml of the solution. Benzyl alcohol may cause allergic effects. If you have liver or kidney disease, or if you are pregnant or breastfeeding, consult the doctor or pharmacist. This is because large amounts of benzyl alcohol can build up in your body and may cause side effects (called 'metabolic acidosis').

This medicine also contains sesame oil, which may rarely cause a severe allergic reaction.

3. HOW SHOULD THE MEDICINE BE USED?

Always use according to the doctor's instructions.

Check with the doctor or pharmacist if you are uncertain. The dosage and treatment regimen will be determined by the doctor only.

Do not exceed the recommended dosage.

Do not swallow.

Your doctor will decide how much Haldol Decanoas you need and for how long, and will adjust the dosage in accordance with:

- Your age
- Whether you have kidney or liver problems
- Your reaction to Haldol in the past
- Other medicines you are taking.

Haldol Decanoas will be administered by a doctor or nurse. Intended for intramuscular injection.

The preparation is intended for adults and is generally injected into the buttocks once a month. Depending on your medical condition, the doctor may only inject part of the ampoule at the start of treatment. Later, the doctor may change the amount of injected medicine or the duration of time between injections, until the desired effect is achieved. After receiving the first injection, some time (3 to 9 days) may pass until you feel the full effect of the medicine.

The medicine is not intended for children.

If you took an overdose or if a child has accidentally swallowed the medicine, refer immediately to a doctor or immediately proceed to a hospital emergency room and bring the package of the medicine with you.

If you forgot to take this medicine at the required time, refer to a doctor and ask him what you should do.

How can you contribute to the success of the treatment? Adhere to the treatment regimen as recommended by the doctor. Even if there is an improvement in your health, do not stop treatment with the medicine without consulting with your doctor or pharmacist.

Do not take medicines in the dark! Check the label and the dose each time you take medicine. Wear glasses if you need them. If you have further questions regarding use of the medicine, consult the doctor or pharmacist.

4. SIDE EFFECTS

As with any medicine, use of Haldol Decanoas may cause side effects in some users. Do not be alarmed by the list of side effects. You may not suffer from any of them.

Look out for serious side effects

Inform your doctor straight away if you notice or suspect any of the following effects. You may need urgent medical treatment.

Heart problems:

- Abnormal heart rhythm – this effect stops the normal heart activity and may cause loss of consciousness
- Abnormally fast heart rate
- Extra heartbeats.

Heart problems are uncommon in people taking Haldol Decanoas (may occur in up to 1 in 100 users). Cases of sudden death have occurred in patients taking this medicine, but the exact frequency of these cases of death is unknown. Cardiac arrest (the heart stops beating) has also occurred in people taking antipsychotic medicines.

A serious problem called neuroleptic malignant syndrome. This syndrome causes a high fever, severe muscle stiffness, confusion and loss of consciousness. The exact frequency of these side effects among people taking Haldol Decanoas is unknown.

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 tremor or stiffness, a shuffling walk
- Inability to move
- Lack of normal facial expression, an expression that sometimes looks like a mask.

These effects are very common in people taking Haldol Decanoas (may occur in more than 1 in 10 users). If you suffer from any of these effects, you may be given an additional medicine.

Severe allergic reaction that may include:

- Swelling of the face, lips, mouth, tongue or throat
 - Difficulty swallowing or breathing
 - Itchy rash (hives).
- The exact frequency of an allergic reaction in people taking Haldol Decanoas is unknown.

Blood clots in the veins, usually in the legs (deep vein thrombosis – 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 travel to the lungs, causing chest pain and breathing difficulties. Blood clots can be very serious, so inform the doctor straight away if you notice any of these problems.

Tell your doctor straight away if you notice any of the serious side effects described above.

Other side effects

Inform your doctor if you notice or suspect any of the following side effects.

Common side effects

- effects that occur in 1-10 in 100 users:
- Depression
- Difficulty sleeping or feeling sleepy
- Constipation
- Dry mouth or increased salivation
- Sexual function problems
- Irritation, pain or collection of pus (abscess) in the injection site
- Weight gain.

Uncommon side effects

- effects that occur in 1-10 in 1,000 users:
- Abnormal muscle tension
- Headache
- Upward movement of the eyes or fast eye movements that you cannot control
- Problems with vision, such as blurred vision.

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

- 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)
- Feeling agitated or confused
- Fits
- Feeling dizzy, including upon sitting up or standing up
- Low blood pressure
- Problems that could cause difficulty breathing, such as:
 - Swelling around the voice box, or brief spasm of the vocal cords that can affect speech
 - Narrowed airways in the lungs
 - Shortness of breath
- Nausea, vomiting
- Changes in the blood, such as:
 - Effects on blood cells – low count of all types of blood cells, including severe decreases in the number of white blood cells and low number of platelets (cells that help blood to clot)
 - High level of certain hormones in the blood – prolactin and antidiuretic hormone (syndrome of inappropriate antidiuretic hormone secretion)
 - Low level of sugar in the blood
- Liver changes that show up in blood tests and other liver problems, such as:
 - Yellowing of the skin or whites of the eyes (jaundice)
 - Inflamed liver
 - Sudden liver failure
- Decreased bile flow in the bile duct
- Skin problems, such as:
 - Rash or itching
 - Increased sensitivity to sunlight
 - Flaking or peeling skin

- Inflamed small blood vessels, leading to a skin rash with small red or purple bumps

- Excessive sweating
- Breakdown of muscle tissue (rhabdomyolysis)
- Muscle spasms, twitching or contractions that you cannot control, including a spasm in the neck causing the head to twist to one side
- Difficulty or inability to open the mouth
- Stiff muscles and joints
- Inability to pass urine or empty the bladder completely
- Persistent and painful erection of the penis
- Difficulty reaching and maintaining an erection (impotence)
- Loss of sex drive or decreased sex drive
- Changes in menstrual cycle (periods), such as no periods, or long, heavy, painful periods
- Breast problems, such as:
 - Pain or discomfort
 - Unexpected production of breast milk
 - Enlarged breasts in men
- Swelling caused by fluid buildup in the body
- High or low body temperature
- Problems walking
- Weight loss.

Reporting side effects

Side effects can be reported to the Ministry of Health by clicking on the link "Report Side Effects of Drug Treatment" found on the Ministry of Health homepage (www.health.gov.il) that directs you to the online form for reporting side effects, or by entering the link: <https://sideeffects.health.gov.il/>

5. HOW SHOULD THE MEDICINE BE STORED?

Avoid poisoning! This medicine, and any other medicine, must be kept in a safe place out of the reach of children and/or infants to avoid poisoning. Do not induce vomiting unless explicitly instructed to do so by the doctor. Do not use the medicine after the expiry date (exp. date) that appears on the package. The expiry date refers to the last day of that month. Store at a temperature below 30°C. Protect from light. Store in a dry place.

6. FURTHER INFORMATION

In addition to the active ingredient, the medicine also contains: benzyl alcohol and purified sesame oil.

What the medicine looks like and the contents of the package: The ampoules contain a viscous, amber-colored solution. The ampoules are packaged in a tray, provided in a carton box.

Importer and Registration Holder and address: J-C Health Care Ltd., Kibbutz Shefayim 6099000, Israel.

Registration number of the medicine in the National Drug Registry of the Ministry of Health: 032-50-22745-01

Revised in February 2021 according to MOH's guidelines.

מידע לצוות הרפואי מعلومات للطاقم الطبي

Any unused medicinal product or waste material should be disposed of in accordance with local requirements.

Importer and Registration Holder: J-C Health Care Ltd., Kibbutz Shefayim 6099000, Israel.

Registration Number: 032-5022745-01

Revised in February 2021 according to MOH's guidelines.

PHARMACEUTICAL PARTICULARS

1. List of Excipients

Benzyl alcohol, sesame oil refined.

2. Incompatibilities

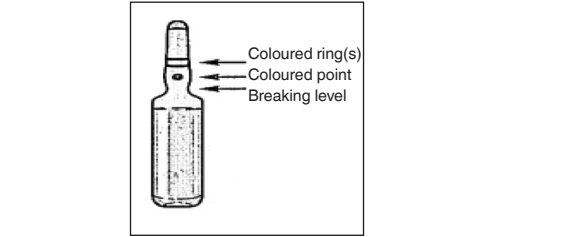
Not applicable.

3. Special Precautions for Storage

Store below 30°C.
Protect from light.
Keep out of the sight and reach of children.

4. Nature and Contents of Container

HALDOL DECANOAS 100 mg/ml is supplied in 1 ml amber-coloured type I glass ampoules. Packs of 5 ampoules.



Instructions for Use and Handling

- Before using the ampoule, roll it briefly between both hand palms to warm up the product.
- Hold the ampoule between the thumb and index finger, leaving the tip of the ampoule free.
- With the other hand, hold the tip of ampoule putting the index finger against the neck of ampoule, and the thumb on the coloured point parallel to the identification coloured rings.
- Keeping the thumb on the point, sharply break the tip of ampoule while holding firmly the other part of the ampoule in the hand.

