

**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 injection**

Each ampoule contains 1 ml.

Each 1 ml contains:

Haloperidol 100 mg (as decanoate)

Inactive and allergenic ingredients in the preparation – See section 2 “Important information regarding some of the ingredients of the medicine” and 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.

## **1. WHAT IS THE MEDICINE INTENDED FOR?**

Haldol Decanoas is intended for maintenance treatment of schizophrenia and schizoaffective disorder in adult patients currently stabilized with oral haloperidol.

**Therapeutic group:** Haloperidol belongs to the anti-psychotics group of the butyrophenone family.

## **2. BEFORE USING THE MEDICINE**

**Do not use the medicine if:**

- You are sensitive (allergic) to the active ingredient (haloperidol) or to any of the additional ingredients contained in the medicine, (see section 6 “Further information”).
- 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 are taking one of the medicines appearing on the list of medicines that should not be taken with Haldol Decanoas (see “Drug interactions” in section 2).

This medicine must not be used if any of the above applies 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 Decanoas 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.

Talk to your doctor before being given Haldol Decanoas if you are elderly, particularly if you have dementia.

### **Before using Haldol Decanoas, tell the doctor if:**

- You have a slow heartbeat, a heart disease, or if anyone in your close family has died suddenly of heart problems.
- You have low blood pressure, or you feel dizzy upon sitting up or standing up.
- You have a low level of potassium or magnesium (or another electrolyte) in the blood. Your doctor will decide how to treat this.
- 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.
- You have problems with your kidneys, liver or thyroid gland.
- You have epilepsy or have ever had fits (convulsions).
- You have 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 have a history of blood clots, or if someone in your family has a history of blood clots.
- You have depression.

You may need to be more closely monitored, and the dosage of Haldol Decanoas you are given may have to be altered.

If you are not sure if any of the above conditions apply to you, talk to your doctor or pharmacist before you are given Haldol Decanoas.

### **Children and adolescents**

Haldol Decanoas should not be used in children and adolescents below 18 years. This is because the medicine has not been studied in these age groups.

### **Tests and follow-up**

Your doctor may want to refer you for an electrocardiogram (ECG) before or during your treatment with Haldol Decanoas. The ECG 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.

### **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 Decanoas if you are taking certain medicines to treat:**

- Problems with your heartbeat (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, 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 (to treat 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 use Haldol Decanoas (see section 2 "Do not use the medicine if").

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

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

- Fever you can't explain or movements you can't control
- Confused, disoriented, a headache, balance problems and feel sleepy.

These are signs of a serious condition.

**Certain medicines may affect the way that Haldol Decanoas works or may make heart problems more likely.**

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 Decanoas can affect the way the following types of medicine work:**

Tell your doctor if you are taking medicines for:

- Calming you down or help with sleep disorders (tranquillizers)
- Treating pain (strong painkillers)
- Treating depression (tricyclic antidepressants)
- Lowering blood pressure (such as guanethidine and methyldopa)
- 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 let your doctor know how much 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. Your doctor may advise you not to use Haldol Decanoas while you are pregnant.

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
- Being sleepy or agitated
- Problems breathing or feeding

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 Decanoas may increase the 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 machines. Side effects, such as feeling sleepy, may affect your alertness, particularly when you first start treatment or after a high dose. Do not drive or use any tools or machines 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. Ask your doctor or pharmacist for advice if you have liver or kidney disease, or if you are pregnant or breastfeeding. 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 about the dosage and treatment regimen of the preparation.

The dosage and treatment regimen will be determined by the doctor only, and your doctor may give you a type of Haldol to take by mouth.

**Do not exceed the recommended dosage.**

Do not swallow.

Your dose of Haldol Decanoas will depend on:

- Your age
- Whether you have problems with your kidneys or liver
- Your reaction to Haloperidol in the past
- Other medicines you are taking.

**Adults**

- Your starting dosage will normally be between 25 mg and 150 mg.
- Your doctor may adjust the dose by up to 50 mg every 4 weeks to find the dose that suits you best (normally between 50 mg and 200 mg every 4 weeks).
- You will not be given more than 300 mg every 4 weeks.

**The elderly**

- Elderly people will normally start on a lower dose, usually between 12.5 mg and 25 mg every 4 weeks.
- The dosage may be adjusted, until your doctor finds the dosage that best suits you (normally between 25 mg and 75 mg every 4 weeks).
- You will only be given a higher dose than 75 mg every 4 weeks if your doctor decides it is safe to do so.

**How will treatment with Haldol Decanoas be given to you**

Haldol Decanoas will be given by a doctor or nurse. It is for intramuscular use, and is given as an injection deep into a muscle. A single dose of Haldol Decanoas will normally last for 4 weeks. Haldol Decanoas must not be injected into a vein.

**If you accidentally receive a higher dosage**

A doctor or nurse will give this medicine to you, so it is unlikely that you will be given too much. If you are worried, tell the doctor or nurse.

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

**If you missed a scheduled dose of Haldol Decanoas or you stopped treatment**

You should not stop treatment with this medicine unless told to do so by your doctor as your symptoms may return. If you miss an appointment, contact your doctor right away to schedule a new appointment.

Adhere to the treatment regimen as recommended by the doctor.

**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 heartbeat
- Extra heartbeats
- Prolonged QT interval syndrome

Heart problems are uncommon in people taking Haldol Decanoas (may affect up to 1 in 100 people). Sudden deaths have occurred in patients using 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 this side effect in 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
- Being unable 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 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).

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 move to the lungs, causing chest pain and difficulty in breathing. 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.

### **Additional side effects**

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

**Common side effects** – effects that occur up to 1 in 10 users:

- Depression
- Difficulty sleeping or feeling sleepy
- Constipation
- Dry mouth or increased saliva
- Sexual function problems
- Irritation, pain or collection of pus (abscess) where the injection is given
- Weight gain.

**Uncommon side effects** – effects that occur in up to 1 in 100 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.

**Side effects of unknown frequency** – effects whose frequency has not been determined:

- 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 (seizures)
- 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 affects speaking
  - Narrowed airways in the lungs
  - Being short 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
- Changes that show up in blood tests of the liver 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
- Being unable to pass urine or empty the bladder completely
- Persistent and painful erection of the penis
- Difficulty getting and keeping 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.

**If a side effect occurs, if one of the side effects worsens or if you are suffering from a side effect not mentioned in the leaflet, consult the doctor.**

### **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](http://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 and sight 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.

## **6. FURTHER INFORMATION**

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

**What the medicine looks like and the contents of the package:** The ampoules contain a viscous, amber-colored solution. Each package contains 5 ampoules in a tray.

**Manufacturer:** Glaxo Smith Kline Manufacturing S.P.A., Strada Provinciale Asolana N.90, San Polo de Torile, 43056, Parma, Italy.

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

**Registration number of the medicine in the National Drug Registry of the**

**Ministry of Health:**

032-50-22745-00

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