PATIENT PACKAGE INSERT IN ACCORDANCE WITH THE PHARMACISTS' REGULATIONS (PREPARATIONS) – 1986

The medicine is dispensed with a doctor's prescription only

HALDOL® 2 mg/ml Drops

Active ingredient

Each 1 ml (20 drops) contains haloperidol 2 mg (haloperidol 2 mg/1 ml).

Inactive ingredients and allergens 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 is indicated in adult patients aged 18 years and above for:

- Treatment of schizophrenia and schizoaffective disorder.
- Acute treatment of delirium when non-pharmacological treatments have failed.
- Treatment of moderate to severe manic episodes associated with bipolar I disorder when other treatments cannot be used.
- Treatment of acute psychomotor agitation associated with psychotic disorder or manic episodes of bipolar I disorder.
- Treatment of persistent aggression and psychotic symptoms in patients with moderate to severe Alzheimer's dementia and vascular dementia when non-pharmacological treatments have failed and when there is a risk of harm to self or others.
- Treatment of tic disorders, including Tourette's syndrome, in patients with severe impairment after educational, psychological and other pharmacological treatments have failed.
- Treatment of mild to moderate chorea in Huntington's disease, when other medicinal products are ineffective or not tolerated.

In paediatric patients for:

- Treatment of schizophrenia in adolescents aged 13 to 17 years when other pharmacological treatments have failed or are not tolerated.
- Treatment of severe, persistent aggression in children and adolescents aged 6 to 17 years with autism or pervasive developmental disorders, when other treatments have failed or are not tolerated.
- Treatment of Tic disorders, including Tourette's syndrome, in children and adolescents aged 10 to 17 years with severe impairment after educational, psychological and other pharmacological treatments have failed.

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 (haloperidol) or to any of the other 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 ‘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 (see section 2 “Drug interactions”).

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

Special warnings regarding use of the medicine

Serious side effects

Haldol can cause problems with the heart, problems controlling body or limb movements and a serious side effect called ‘neuroleptic malignant syndrome’. Haldol 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 ‘Look out for serious side effects’ in section 4.

Elderly people and people with dementia

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

Talk to your doctor before taking Haldol if you are elderly, particularly if you have dementia.

Before using Haldol, tell the doctor if:

- you have slow heartbeats, heart disease or anyone in your close family 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 have 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 epilepsy or have ever had fits (convulsions).
- you have problems with your kidneys, liver or thyroid gland.

- you have a high level of the hormone ‘prolactin’ in your blood, or cancer that may be caused by high prolactin levels (such as breast cancer).
- you have a history of blood clots, or someone else in your family has a history of blood clots.
- you have depression or bipolar disorder and you start to feel depressed.

You may need to be more closely monitored, and the amount of Haldol you take may have to be altered.

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

Children below 6 years of age
Haldol should not be used in children below 6 years of age. This is because the medicine has not been studied adequately in this age group.

Tests and follow-up
Your doctor may want to refer you for an electrocardiogram test (ECG) before or during your treatment with Haldol. 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.

Drug interactions
If you are taking, or have recently taken, other medicines, including non-prescription medicines and nutritional supplements, tell the doctor or pharmacist.
Do not take Haldol if you are taking certain medicines to treat:
- Problems with the heartbeat (such as amiodarone, dofetilide, disopyramide, dronedarone, ibutilide, quinidine, 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 (to treat chest pain or to lower blood pressure) or methadone (to relieve pain 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 medicines and do not take Haldol (see section 2 “Do not use the medicine if”).

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

Special monitoring is needed if you are taking both medicines together. Inform your doctor straight away and stop taking both medicines at the same time, if you suffer from:

- fever you cannot explain or movements you cannot control
- confusion, disorientation, headache, balance problems and feeling sleepy

These are signs of a serious condition.

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

Tell your 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 you stop smoking)
- 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 tell your doctor if you are taking any other medicines to lower blood pressure, such as water tablets (diuretics).

Your doctor may have to change the dose of Haldol 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:

- Calming you down or helping you to sleep (tranquillisers)
- 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)

Consult with your doctor before taking Haldol if you are taking any of these medicines.

Use of the medicine and food

Haldol 2 mg/ml Drops can be mixed with some water before taking, but do not mix Haldol 2 mg/ml Drops with any other liquid.

Use of the medicine and alcohol consumption
Drinking alcohol while taking Haldol might make you feel sleepy and less alert. This means you should be careful how much alcohol you drink. Consult with your doctor about drinking alcohol while taking Haldol, and let your doctor know how much you drink.

Pregnancy, breastfeeding and fertility
Pregnancy - If you are pregnant, think you may be pregnant or are planning to become pregnant, ask the doctor for advice. Your doctor may advise you not to take Haldol while you are pregnant.
The following problems may occur in newborn babies of mothers that take Haldol in the last 3 months of their pregnancy (the last trimester):
- Muscle tremors, stiff or weak muscles
- Sleepiness or agitation
- Problems breathing or feeding.

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

Breastfeeding - Consult with the doctor if you are breastfeeding or planning to breastfeed. 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.

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 using machines
Haldol 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 taking 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
Haldol 2 mg/ml Drops contains the ingredient methyl parahydroxybenzoate. This substance may cause an allergic reaction. The reaction may occur some time after you start taking Haldol 2 mg/ml Drops.

3. HOW SHOULD THE MEDICINE BE USED?

Always use the preparation according to the doctor's instructions. Check with the doctor or pharmacist if you are uncertain about the dosage and treatment regimen.
The dosage and treatment regimen will be determined by the doctor only.
Your doctor will tell you how much Haldol to take and for how long. Your doctor will also tell you whether to take Haldol one or more times a day. It may be some time before you feel the full effect of the medicine. Your doctor will normally start you on a low dose, and then adjust the dose to suit you. It is very important you take the correct amount.
Your dose of haloperidol will depend on:
- Your age

- The disorder you are being treated for
- Whether you have problems with your kidneys or liver
- Other medicines you are taking.

Adults
- Your starting dose will normally be between 0.5 mg and 10 mg each day.
- Your doctor may adjust the dose to find the dose that suits you best.
- The highest dose for adults depends on the medical condition you are being treated for and varies between 5 mg and 20 mg each day.

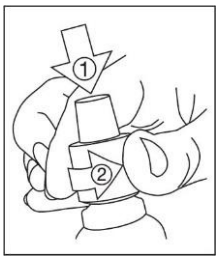
Elderly people
- Elderly people will normally start on 0.5 mg each day or half the lowest adult dose.
- The Haldol dose will then be adjusted until the doctor finds the dose that suits you best.
- The highest dose elderly people should take is 5 mg each day, unless your doctor decides a higher dose is needed.

Children and adolescents 6 to 17 years of age
- Your dose will normally be between 0.5 mg and 3 mg each day.
- Adolescents up to 17 years of age being treated for schizophrenia or behavioural problems may take a higher dose, up to 5 mg each day.

Do not exceed the recommended dose.

Haldol is intended to be taken orally.
You can take the drops after mixing them in a small amount of water; do not mix them with a different fluid. It is very important to take the right amount of Haldol.

Instructions for opening the bottle:
- The bottle is closed with a safety cap to prevent random opening by children.
- To remove the cap, press downwards, while turning counterclockwise.
- After opening, turn the bottle upside down over a spoon.
- Gently press the sides of the bottle and count the number of drops you need to take.
- Drink the solution straight away.
- Close the bottle.



If you accidentally take a higher dosage
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.
One or more of the following signs may occur: sedation, acute tremor or overly rigid muscles.

If you forget to take the medicine
If you forgot to take this medicine at the scheduled time, do not take a double dose. Take the next dose at the usual time and consult the doctor. Continue taking the medicine according to the doctor's instructions.
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.

If you stop taking Haldol
Unless your doctor instructs you otherwise, you should stop taking Haldol gradually. Stopping treatment suddenly may cause effects, such as:
- Nausea and vomiting
- Difficulty sleeping.

Adhere to the treatment regimen according to the doctor's instructions.

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 2 mg/ml Drops may cause side effects in some users. Do not be alarmed when reading 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 stops the heart working normally and may cause loss of consciousness
- Abnormally fast heart rate
- Extra heartbeats
- Prolonged QT interval

Heart problems are uncommon in people taking Haldol (may occur in up to one user in 100). 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 effect causes a high fever, severe muscle stiffness, confusion and loss of consciousness. It is rare in people taking Haldol (may occur in up to one user in 1,000).

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 (may occur in more than 1 in 10 users). If you get 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).

An allergic reaction is uncommon in people taking Haldol (may occur in up to one user in 100).

Blood clots in the veins, usually in the legs (deep vein thrombosis - DVT). Blood clots 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 breathing difficulties. Blood clots can be very serious, so inform your doctor straight away if you notice any of these problems.

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

Other side effects

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

Very common side effects - effects that occur in more than one user in 10:
- Feeling agitated
- Difficulty sleeping
- Headache.

Common side effects - effects that occur in up to one user in 10:
- Serious mental health disorder, 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
- Vision problems, 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 for liver function.

Uncommon side effects - effects that occur in up to one user in 100:
- Effects on blood cells - low number of all blood cells, including severe decreases in white blood cell count 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 movements 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 a 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 (monthly periods), such as absence of monthly periods, or long, heavy, painful periods
- Unexpected production of breast milk
- Breast pain or discomfort
- High body temperature
- Swelling caused by fluid buildup in the body.

Rare side effects - effects that occur in up to one user in 1,000:
- 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
- Sexual function problems.

Side effects of unknown frequency - effects whose frequency has not been determined:
- 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 accompanied by small red or purple bumps

- Breakdown of muscle tissue (rhabdomyolysis)
- Persistent and painful erection of the penis
- Enlarged breasts in men
- Low body temperature.

If a side effect occurs, if one of the side effects worsens or if you suffer from a side effect not mentioned in the leaflet, consult with 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) 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.

Storage conditions: Store below 30°C. Do not freeze.
After first opening the bottle, do not use Haldol 2 mg/ml Drops for more than 3 months.

6. FURTHER INFORMATION

- **In addition to the active ingredient, the medicine also contains:**
  Lactic acid, methylparahydroxybenzoate and purified water.
- What does the medicine look like and what are the contents of the package:
  The preparation comes in a package of 15 ml or 30 ml.
  The preparation comes in a bottle with a drop counter, and contains a clear and colorless solution.
  Not all pack sizes may be marketed.
- **Manufacturer:** Janssen Pharmaceutica N.V., Turnhoutseweg 30, B-2340, Beerse, Belguim.
- **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:** 029-70-25163-00

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