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

The medicine is dispensed with a doctor's prescription only

Haloper 0.5 mg tablets

Haloper 5 mg tablets

Haloper 10 mg tablets

Each tablet of Haloper 0.5 contains:
Haloperidol 0.5 mg.

Each tablet of Haloper 5 contains:
Haloperidol 5 mg

Each tablet of Haloper 10 contains:
Haloperidol 10 mg

For inactive ingredients and allergens in the preparation – see section 2 "Important information about some of the ingredients of the medicine" and section 6 "Additional information".

Read the entire leaflet carefully before using the medicine. This leaflet contains concise information about the medicine. If you have any other questions, refer to the doctor or the pharmacist.
This medicine has been prescribed for treatment of your illness. Do not pass it on to others. It may harm them even if it seems to you that their medical condition is similar.

1. What is the medicine intended for?

Haloper is intended for adult patients from 18 years of age and above:
- For treatment of schizophrenia and schizoaffective disorder.
- For acute treatment of acute confusion (delirium) after failure of non-pharmacological treatments.
- For treatment of moderate to severe manic episodes related to bipolar disorder, when other treatments cannot be used.
- For treatment of acute psychomotor agitation related to a psychotic disorder or to manic episodes due to bipolar disorder.
- For treatment of persistent aggression and psychotic symptoms in patients with moderate to severe dementia due to Alzheimer's disease and vascular dementia after failure of non-pharmacological treatments and when there is a risk of self-harm or harm to others.
- For treatment of tic disorders, including Tourette's syndrome, in patients with severe impairment after failure of other educational, psychological and pharmacological treatments.
- For treatment of mild to moderate chorea in Huntington's disease, when other medical preparations are ineffective or intolerable.

For pediatric patients:
- For treatment of schizophrenia in adolescents aged 13 to 17 when other pharmacological treatments have failed or are intolerable.
- For treatment of persistent severe aggression in children and adolescents aged 6 to 17 with autism or with pervasive developmental disorders, when other pharmacological treatments have failed or are intolerable.
- For treatment of tic disorders, including Tourette's syndrome, in children and adolescents aged 10 to 17 with severe impairment after failure of other educational, psychological and pharmacological treatments.

Therapeutic class: Haloper belongs to a group of antipsychotic substances from the class of butyrophenones.

2. Before using the medicine:

☒ Do not use this medicine if:
- You are sensitive (allergic) to the active ingredient or to any of the other ingredients this medicine contains (see section 6 – "Additional information").
- You are less aware of things happening around you or your reactions are becoming unusually slow.
- You suffer from Parkinson's disease.
- You suffer from Lewy body dementia.
- You suffer from a neurodegenerative brain disease – progressive supranuclear palsy (PSP).
- You suffer from a cardiac disorder known as "long QT syndrome" or any other heart rhythm problem that causes an abnormal finding on an ECG (electrocardiogram) chart.
- You suffer from heart failure or have had a heart attack recently.
- You suffer from untreated low blood potassium level.
- You are taking one of the medicines in the list of medicines that should not be taken with Haloper (see section 2 "Drug Interactions").

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

☒ Special warnings regarding the use of the medicine: ☒ Severe side effects
Haloper can cause heart problems, problems controlling body or limb movements, and a severe side effect called "neuroleptic malignant syndrome". This effect can also cause severe allergic reactions and blood clots. You should be aware of the severe side effects while taking Haloper, because you may need urgent medical treatment (see "Be aware of severe side effects" in section 4).

☒ Elderly people and people with dementia
A small increase in cases of death and stroke has been reported in elderly people with dementia who are taking antipsychotic medicines. Talk to your doctor before taking Haloper if you are elderly, particularly if you suffer from dementia.

☒ Before using Haloper, tell the doctor if you have:
- Slow heart rate, heart disease or if any of your immediate family members died suddenly of heart problems.
- Low blood pressure or if you feel dizzy when changing to a sitting or standing position.
- Low blood potassium or magnesium (or another electrolyte) in the blood. The doctor will determine how to treat it.
- Or if you have ever had cerebral hemorrhage, or if the doctor has told you that your risk of stroke is higher than that of other people.
- Epilepsy or if you have ever suffered from convulsions (spasms).
- Kidney, liver or thyroid problems (hyperthyroidism).
- High level of the hormone prolactin in the blood or cancer that can be caused by high levels of prolactin (such as breast cancer).
- A history of blood clots or family history of blood clots.
- Depression or bipolar disorder and you start to feel depressed.

You may need closer monitoring and your dosage of Haloper may need to be changed.
If you are not sure if any of the conditions detailed above is relevant to you, consult your doctor or pharmacist before taking Haloper.

☒ Children below 6 years of age
Haloper should not be used in children under 6 years of age, as the medicine has not been properly studied in this age group.

☒ Tests and follow-up
Your doctor may refer you to an electrocardiogram test (ECG) before or during the treatment with Haloper, to check the electrical activity of the heart.
Your doctor may also refer you to a blood test to check the levels of potassium or magnesium (or another electrolyte) in the blood before or during the treatment with Haloper.

☒ Drug interactions
If you are taking, or have recently taken, other medicines including non-prescription medicines and nutritional supplements, tell the doctor or the pharmacist.
Do not take Haloper if you are taking certain medicines to treat:
- Heart rhythm problems (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, 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 (for the treatment of chest pain or for lowering blood pressure) or methadone (for pain relief or for the treatment of drug addiction).
These medicines may increase the risk of heart problems; therefore, if you are taking any of these medicines, do not take Haloper and consult with your doctor (see the section "Do not use this medicine if").
Special monitoring may be required if you are taking lithium and Haloper concomitantly.
Special monitoring is needed if you are taking the two medicines concomitantly. Tell your doctor immediately and stop taking both medicines concomitantly if you suffer from:
- Unexplained fever or uncontrolled movements.
- Confusion, disorientation, headache, balance problems and a sensation of sleepiness.

These are all signs of a serious condition.
Certain medicines may affect the way Haloper works or increase the risk of heart problems. Tell your doctor if you are taking:
- Algrazopride or buspirone (for the treatment of anxiety).
- Duloxetine, fluoxetine, fluvoxamine, nefazodone, paroxetine, sertraline, St. John's Wort (hypericum perforatum) or venlafaxine (for the treatment of depression).
- Bupropion (for the treatment of depression or to support smoking cessation).
- Carbamazepine, phenobarbital or phenytoin (for the treatment of epilepsy).
- Rifampicin (for the treatment of bacterial infections).
- Itraconazole, posaconazole or voriconazole (for the treatment of fungal infections).
- Ketoconazole tablets (for the treatment of Cushing's syndrome).
- Indinavir, ritonavir or saquinavir (for the treatment of human immunodeficiency virus, HIV).
- Chlorpromazine or promethazine (for the treatment of nausea and vomiting).
- Verapamil (for the treatment of hypertension or heart problems).

Furthermore, tell your doctor if you are taking other medicines to lower blood pressure, such as diuretic medicines.
Your doctor may need to change your dosage of Haloper if you are taking one of these medicines.

Haloper can affect the way medicines of the following types work. Tell your doctor if you are taking medicines:
- For calming or assistance with sleep disturbances (tranquilizers).
- For pain treatment (strong analgesics).
- For treatment of depression (tricyclic antidepressants).
- For lowering blood pressure (such as: guanethidine and methyldopa).
- For treatment of severe allergic reactions (adrenaline).
- For treatment of attention deficit hyperactivity disorders (ADHD) or narcolepsy (known as stimulant medications).
- For treatment of Parkinson's (such as: levodopa).
- For blood thinning medicines.

Consult your doctor before taking Haloper if you are taking any of these medicines.
☒ Use of the medicine and food
The medicine may be taken with or without food.
☒ Use of the medicine and alcohol consumption
Drinking alcohol while taking Haloper can cause sleepiness and decreased alertness. This means that you need to be careful with the amount of alcohol that you drink. Consult your doctor regarding alcohol consumption while taking Haloper 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 consultation. Your doctor may advise you not to take Haloper during pregnancy.
Tremor, muscle stiffness or weakness; sleepiness or restlessness; difficulty breathing or difficulty feeding, may occur in newborns of mothers who have taken Haloper during the last trimester of pregnancy.
The exact prevalence of these problems is unknown. If you have taken Haloper during pregnancy and your baby develops any of these side effects, refer to a doctor.
Breastfeeding – consult your doctor if you are breastfeeding or planning to breastfeed, as small amounts of the medicine may pass into breast milk and from there to your baby. You will discuss with you the risks and benefits of breastfeeding when you are taking Haloper.
Fertility – Haloper may increase the levels of the hormone prolactin, which may affect male and female fertility. Consult your doctor if you have questions about this.
☒ Driving and operating machinery
Haloper may affect the ability to drive and use tools and machinery. Side effects, such as a sensation of sleepiness, may impair alertness, especially at the beginning of treatment or after administering a high dosage. Do not drive or operate machinery without consulting your doctor.
☒ Important information about some of the ingredients of the medicine
Haloper contains lactose. If you have been told by your doctor that you have an intolerance to certain sugars, consult your doctor before starting to use Haloper tablets.

3. How should you use the medicine?

Always use the preparation according to the doctor's instructions. Check with the doctor or pharmacist if you are uncertain about the dosage and how to use the preparation. The dosage and treatment regimen will be determined only by the doctor.
The doctor will try to achieve much Haloper to take and for how long. Furthermore, the doctor will tell you whether to take Haloper once a day or several times a day. It may take some time before you feel the full effect of the medicine. The doctor will usually start with a low dosage and then adjust the dose to the suitable dosage for you. It is very important that you take the right amount.
The dosage of Haloper given to you will depend:
- On your age
- On the disorder for which you are receiving this treatment
- On whether you have kidney or liver problems
- On any additional medicines you are taking

Adults
- Your starting dosage will usually be 0.5 mg to 10 mg daily.
- Your doctor may adjust the dosage, to check which dosage is most suitable for you.
- The maximum dosage for adults should depend on the medical condition for which you are receiving the treatment and ranges from 5 mg to 20 mg daily.

The elderly
- Elderly people start treatment at a dosage of 0.5 mg daily or half of the minimum adult dosage.
- The number of tablets you are taking will be adjusted for you until the doctor finds the most suitable dosage for you.
- The maximum dosage that the elderly can take is 5 mg daily, unless the doctor decides that a higher dosage is needed.

Children and adolescents aged 6-17
- Your dosage will usually be 0.5 mg to 3 mg daily.
- Adolescents up to 17 years of age who are receiving treatment for schizophrenia or behavioral problems may take a higher dosage of up to 5 mg daily.

Do not exceed the recommended dose.
Method of administration – Haloper is intended for oral administration. The medicine may be taken with or without food. The medicine should be swallowed with some water. Crushing/halving/chewing: do not chew, the tablet is intended to be swallowed. If needed, the tablet may be halved, crushed or pulverized.
If you accidentally took a higher dosage
If you took an overdose or if someone else accidentally swallowed this medicine, go immediately to the doctor or to a hospital emergency room and take the package of the medicine with you. When taking an overdose, one or more of the following symptoms may appear: reduced state of alertness, acute tremor or excessive muscle stiffness.
If you forgot to take the medicine
If you forgot to take this medicine at the required time, do not take a double dose. Take the next dose at the usual time and consult a doctor. Then continue to take the medicine according to the doctor's instructions.
Follow the treatment as recommended by the doctor. Even if there is an improvement in your health condition, do not stop treatment with the medicine without consulting the doctor.
If you stop taking the medicine
The treatment with Haloper should be stopped gradually, unless your doctor tells you otherwise. Sudden discontinuation of the treatment may cause effects such as: nausea, vomiting and sleeping difficulties.
Do not take medicines in the dark! Check the label and the dose every time you take a medicine. Wear glasses if you need them.
If you have any other questions regarding the use of the medicine, consult the doctor or the pharmacist.

4. Side effects:

As with any medicine, using Haloper may cause side effects in some users. Do not be alarmed when reading the list of side effects. You may not experience any of them.
Be aware of severe side effects
Tell your doctor immediately if you notice or suspect the occurrence of any of the following effects. You may need urgent medical treatment.
Heart problems:
- Heart rhythm disorder – this effect stops the normal functioning of the heart and may cause loss of consciousness.
- Unusually fast heart rate.
- Extra heartbeats.
- QT interval prolongation syndrome.

Heart problems are uncommon among people taking Haloper (may occur in up to 1 out of 100 users). Cases of sudden death have occurred in patients taking this medicine, but the exact incidence of these cases of death is unknown. Furthermore, cardiac arrest (a condition in which the heart stops beating) has occurred in people taking anti-psychotic medicines.
A severe problem known as "neuroleptic malignant syndrome" – this phenomenon causes high fever, severe muscle stiffness, confusion and loss of consciousness. It is rare among people taking Haloper (may occur in up to 1 out of 1,000 users).

Problem controlling the body or limb movements (extrapyramidal disorder), such as:
- Movements of the mouth, tongue, jaw and sometimes the limbs (tardive dyskinesia).
- Feeling restless or difficulty sitting still, excessive body movements.
- Slow or reduced body movements, spasms or spasmodic movements.
- Tremor or muscle stiffness, swaying gait.
- Inability to move.
- Lack of a normal facial expression, an expression that sometimes looks like a mask.

These effects are very common among people taking Haloper (may occur in more than 1 out of 10 users). If you suffer from one of these effects, you may need to be treated with an additional medicine.
A severe allergic reaction that may include:
- Swelling of the face, lips, mouth, tongue or throat.
- Difficulty swallowing or breathing.
- A rash accompanied by itching (hives).

An allergic reaction is uncommon among people taking Haloper (may occur in up to 1 out of 100 users).
Blood clots in the veins, usually in the legs (deep vein thrombosis or DVT). Blood clots have been reported in people taking antipsychotic medicines. Signs of DVT in the leg include swelling, pain and redness in the leg, but the clot may drift into the lungs, causing chest pain and difficulty breathing. Blood clots may be very serious, therefore tell the doctor immediately if you notice any of these problems.
Tell your doctor immediately if you notice any of the severe side effects listed above.
Additional side effects
Tell your doctor if you notice or suspect the occurrence of any of the following side effects.
Very common side effects – effects that occur in more than one user out of ten:
- Feeling of restlessness.
- Sleeping difficulties.
- Headaches.

Common side effects – effects that occur in 1-10 users out of 100:
- A severe mental disorder such as believing in things that are not real (false thoughts) or seeing, feeling, hearing or smelling things that do not exist (hallucinations).
- Depression.
- Abnormal muscle tension.
- Sensation of dizziness, including when changing to a sitting or standing position.
- Feeling sleepiness.
- Upward eye movement or rapid and uncontrollable eye movements. Vision problems such as blurry vision.
- Low blood pressure.
- Nausea, vomiting, constipation.
- Dry mouth or excessive salivation.
- Skin rash.
- Inability to urinate or empty the bladder completely.
- Difficulty in obtaining and maintaining an erection (impotence).
- Weight gain or loss.
- Changes that appear in blood tests for liver function.

Uncommon side effects – effects that occur in 1-10 users out of 1,000:
- 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 clotting).
- A sense of confusion.
- Loss of libido or increased libido.
- Convulsions (spasms).
- Stiffness in the muscles and joints.
- Muscle spasms, spasmodic movements or uncontrollable cramps, including a spasm in the neck that causes the head to rotate to one side.
- Walking problems.
- Shortness of breath.
- Hepatitis or liver problem causing yellowing of the skin or eyes (jaundice).
- Increased sensitivity of the skin to sunlight.
- Itch.
- Excessive sweating.
- Changes in menstrual cycles (monthly periods), such as: absence of monthly periods or long, heavy and painful periods.
- Unexpected production of milk in the breasts.
- Pain or discomfort in the breasts.
- High body temperature.
- Swelling caused by fluid accumulation in the body.

Rare side effects – effects that occur in 1-10 out of 10,000 users:
- High level of the hormone prolactin in the blood.
- Narrowing of airways in the lungs causing breathing difficulties.
- Difficulty or inability to open the mouth.
- Sexual dysfunction.

Furthermore, side effects with unknown frequency have been reported – effects whose frequency has not yet been determined:
- High level of anti-diuretic hormone in the blood (a syndrome involving impaired secretion of anti-diuretic hormone).
- Low blood sugar level.
- Swelling around the larynx or a momentary spasm of the vocal cords that may cause difficulty speaking or breathing.
- Sudden liver failure.
- Reduced bile flow in the bile duct.
- Formation of scaly skin or peeling of the skin.
- Inflammation of small blood vessels, leading to a skin rash accompanied by small red or purple bumps.
- Breakdown of muscle tissue (rhabdomyolysis).
- Persistent erection accompanied by pain in 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 your doctor.
Reporting side effects
Side effects may be reported to the Ministry of Health by clicking on the link "Report side effects due to medicinal treatment" found on the Ministry of Health website homepage (www.health.gov.il), which will direct you to the online form for reporting side effects, or by clicking on the following link: https://sideeffects.health.gov.il

5. How to store the medicine?

- Avoid poisoning! This medicine and any other medicine must be kept in a closed place out of the reach and sight of children and/or infants to avoid poisoning. Do not induce vomiting without an explicit instruction from the doctor.
- Do not use the medicine after the expiry date (EXP) appearing on the package. The expiry date refers to the last day of that month.
- Store at a temperature below 25°C. Store in the original package.

6. Additional information:

In addition to the active ingredient, the medicine also contains:
Haloper 0.5:
Lactose, Maize starch, Povidone, Magnesium stearate.
Haloper 5:
Lactose, Maize starch, Povidone, Magnesium stearate, Sunset Yellow FDC Yellow no. 6.
Haloper 10:
Lactose, Maize starch, Povidone, Magnesium stearate, Quinoline Yellow 70 E 104, Indigo Carmine.
What does the medicine look like and what are the contents of the package?
Haloper 0.5: a white-yellowish, round, flat tablet with a score line on one side.
Haloper 5: an orange, round, flat tablet with a score line on both sides.
Haloper 10: a light green, round, flat tablet with a score line on both sides.
The tablets are packed in aluminum blisters, 10 tablets per blister, in a carton package containing 20, 30 or 100 tablets (Haloper 0.5) or 20, 30, 60 or 100 tablets (Haloper 5, 10). Not all package sizes may be marketed.

Name and address of the marketing authorization holder/manufacturer: CTS Chemical Industries Ltd., 3 Hakidma St., Kiryat Malachi.
This leaflet was revised in 06/2023 in accordance with the Ministry of Health guidelines.
Registration numbers of the medicine in the national drug registry of the Ministry of Health:
Haloper 0.5: 1159325918, Haloper 5: 1169525917, Haloper 10: 1159225916

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