



## **Patient package insert according to Pharmacists' Regulations (Preparations) – 1986**

This medicine can be sold with a physician's prescription only

### **Risperidex<sup>®</sup> 1 mg, 3mg, Tablets** **Risperidex<sup>®</sup> 2 mg, 4 mg, Caplets**

**Each tablet/caplet contains** risperidone 1, 2, 3 or 4 mg respectively.

Inactive ingredients and allergens in the medicine - see section 6 "Additional information" and in section 2 "Important information about some of the ingredients of this medicine".

**Read this entire leaflet carefully before using this medicine.** This leaflet contains concise information about the medicine. If you have any further questions, ask the doctor or pharmacist.

This medicine has been prescribed to treat your illness. Do not pass it on to others. It may harm them, even if you think their illness is the same as yours.

#### **1. What is the medicine intended for?**

- For the treatment of schizophrenia and symptoms of psychotic disorders.
- Also effective in maintaining clinical improvement in long-term treatment in patients who have shown an initial response to treatment.
- For the treatment of psychotic manifestations of moderate to severe dementia, due to a history of Alzheimer's disease (short-term treatment up to 6 weeks in a state of persistent aggression) in patients who do not respond to non-pharmacological treatments and when there is a risk of harm to self or others.

Other behavioral disorders:

- For the treatment of behavioral disorders, such as violence, impulsiveness and self-aggression in intellectually disabled children over 5 years of age and adolescents.
- For the treatment of mania in bipolar disorder.

**Therapeutic group:** antipsychotics medicine.

**Risperidex** can help relieve the symptoms of the disease and prevent their recurrence.

Schizophrenia - a condition where the patient can see or feel things that are not there, believe in things that are not true or feel unusually suspicious or confused.

Mania - a condition in bipolar disorder in which the patient can feel very excited, exalted, agitated, enthusiastic or hyperactive.

#### **2. Before using the medicine**

**Do not use the medicine if:**

You are hypersensitive (allergic) to the active ingredient (risperidone) or to any of the other ingredients this medicine contains (see section 6).

**Special warnings regarding the use of the medicine:**

**Before treatment with Risperidex tell your doctor if:**

- You have a heart problem. For example irregular heart rhythm or if you have a tendency for low blood pressure or if you are taking medicines for your blood pressure. **Risperidex** may cause low blood pressure. Your dosage may need to be adjusted.

- You have a risk factor for a stroke, such as high blood pressure, cardiovascular disorders or cerebrovascular problems.
- You have ever suffered from involuntary movements of the tongue, mouth or face.
- You have ever suffered from a condition whose symptoms include high fever, muscle stiffness, sweating or decreased level of consciousness (also known as Neuroleptic malignant syndrome).
- You suffer from Parkinson or dementia.
- You know you have suffered from low white blood cells count in the past (which may or may not have been caused by other medicines).
- You suffer from diabetes.
- You suffer from epilepsy.
- You are a man and have suffered in the past from a prolonged or painful erection.
- You have difficulty regulating your body temperature or suffer from overheating.
- You suffer from kidney problems.
- You suffer from liver problems.
- You suffer from an abnormally high level of the hormone prolactin in your blood or you may suffer from a prolactin-dependent tumor.
- You suffer from the formation of blood clots or your family has a history of blood clots, as antipsychotics have been associated with formation of blood clots.

If you are unsure whether any of the above conditions apply to you, refer to the doctor or pharmacist before taking **Risperidex**.

- A dangerously low number of certain white blood cells needed to protect against infections has been very rarely observed in patients taking a risperidone-containing medicine. Therefore, your doctor may check your white blood cell count.
- Risperidone may cause you to gain weight. Significant weight gain may adversely affect your health. Your doctor should regularly check your body weight.
- As diabetes or worsening of pre-existing diabetes have been observed in patients taking a risperidone containing medicine, your doctor will check for signs of high blood sugar levels. In patients with diabetes, blood glucose levels should be monitored regularly.
- Risperidone commonly increases the levels of the prolactin hormone. This may cause side effects, such as menstrual disorders or fertility problems in women, swelling of breasts in men (see section 4 “Side effects”). If these side effects occur, an evaluation of prolactin levels in the blood is recommended.
- During cataract surgery (a disease of the eye manifested by cloudiness of the eye lens) the pupil of the eye (the black circle in the center of the eye) may not increase to the desired size. Also, the iris (the colored part of the eye) may become floppy during surgery and this may cause eye damage. If you are planning to have an eye surgery, tell the doctor that you are taking this medicine.

#### **Elderly people with dementia:**

In elderly patients with dementia, there is an increased risk of stroke. You should not take **Risperidex** if you have dementia caused by stroke.

During treatment with **Risperidex** you should frequently see the doctor.

You should seek immediate medical help if you or your care-giver notice a sudden change in your mental state or sudden weakness or sudden loss of feeling in the face, arms or legs, especially on one side of the body, or slurred speech, even for a short period of time. These may be signs of a stroke.

#### **Children and adolescents:**

Before starting treatment for behavioral disorder, other causes of aggressive behavior should be ruled out.

If during treatment with **Risperidex** fatigue occurs, a change in the time of administration might improve attention difficulties.

Before starting treatment, the child or adolescent should be weighed and body weight should be monitored regularly during treatment.

A small and inconclusive study has reported a height increase in children who have taken risperidone. But whether this effect was caused by the medicine or by some other reason is unknown.

In clinical studies in children and adolescents suffering from schizophrenia, an increase in blood glucose levels, changes in blood lipid levels, weight gain have been reported.

### **Drug interactions**

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

Especially if you are taking:

- Medicines that act on your brain, such as anti-anxiety medications (benzodiazepines) or certain medicines for pain (opiates), medicines for allergy (certain antihistamines), as risperidone may increase the sedative effect of all of these.
- Medicines that may alter the heart's electrical activity, such as medicines for malaria, medicines for the treatment of arrhythmias, allergy medicines (antihistamines), certain antidepressants or other medicines for mental problems.
- Medicines that cause a slow heart rate.
- Medicines that cause low blood potassium levels (such as certain diuretics).
- Medicines for the treatment of hypertension. Risperidone may lower blood pressure.
- Medicines for the treatment of Parkinson (such as levodopa).
- Medicines that increase the activity of the central nervous system (psychostimulants such as methylphenidate).
- Diuretics for the treatment of heart problems or swelling of body organs due to excessive accumulation of fluids (such as furosemide or chlorothiazide). Risperidone taken alone or with furosemide may increase the risk of stroke or death in elderly patients with dementia.

### **The following medicines may reduce the effect of risperidone:**

- Rifampicin (a medicine for the treatment of certain infections)
- Carbamazepine, phenytoin (medicines for the treatment of epilepsy)
- Phenobarbital

If you start or stop taking these medicines you may need a different dosage of risperidone.

### **The following medicines may increase the effect of risperidone:**

- Quinidine (a medicine for the treatment of certain types of heart disease).
- Antidepressants (such as paroxetine, fluoxetine, tricyclic antidepressants).
- Beta blockers (for instance, to treat high blood pressure).
- Phenothiazines (such as psychosis medications or sedatives).
- Cimetidine, ranitidine (medicines that reduce stomach acidity).
- Itraconazole and ketoconazole (medicines for the treatment of fungal infections).
- Certain medicines for the treatment of HIV/AIDS such as ritonavir.
- Verapamil, for the treatment of high blood pressure and/or abnormal heart rhythm.
- Sertraline and fluvoxamine, medicines for the treatment of depression and other psychiatric disorders.
- Paliperidone (for the treatment of mental disorders).

If you start or stop taking these medicines, you may need a different dosage of risperidone. If you are not sure about any of the above, contact your doctor or pharmacist before taking the medicine.

### **Use of the medicine and food**

The medicine can be taken with or without food.

### **Use of the medicine and alcohol consumption**

You should avoid drinking alcohol during treatment with **Risperidex**.

### **Pregnancy, breastfeeding and fertility**

- If you are pregnant, breastfeeding, think you may be pregnant or are planning to have a baby, consult the doctor who will decide if you can take **Risperidex**.
- The following symptoms may occur in newborn babies of mothers who have used risperidone in the last trimester (last three months of their pregnancy): tremor, muscle stiffness and/or weakness, sleepiness, restlessness, breathing problems or difficulty feeding. If your baby develops any of these symptoms you may need to contact the doctor.
- Risperidone may increase the levels of a hormone called "prolactin", which may affect fertility (see "Side effects").

### **Driving and using machines**

The use of this medicine may cause dizziness, fatigue and vision problems, therefore do not drive a vehicle, operate machinery or tools without first consulting your doctor. As for children, they should be warned about riding a bicycle or playing near roads etc.

### **Important information about some of the ingredients of the medicine:**

**Risperidex** contains lactose. If you have been told in the past by a doctor that you have an intolerance to certain sugars, consult a doctor before commencing treatment.

This medicine contains less than 1 mmole sodium (23 mg) per tablet/caplet, that is to say essentially "sodium-free".

### **3. How to use the medicine?**

Always use this medicine according to the doctor's instructions.

Check with the doctor or pharmacist if you are not sure about the dosage and the manner of treatment with the medicine.

The dosage and manner of treatment will be determined by the doctor only.

The doctor may gradually adjust your dose after administering the first dose, depending on your response to treatment.

Use this medicine at set times as determined by the attending doctor.

In elderly patients, a reduced dosage of **Risperidex** should be used as instructed by the doctor.

Patients suffering from liver or kidney problems: in these patients, a reduced dosage of **Risperidex** should be taken according to the doctor's instructions. **Risperidex** should be used with caution in these patients.

**Do not exceed the recommended dose.**

#### **Method of use:**

The medicine can be taken with or in between meals.

**Method of administration:** Swallow the medicine with water.

**Risperidex 1 mg:** the tablet may be halved. **Risperidex 2, 3, 4 mg:** do not halve the tablet/caplet since there is no score line. There is no information regarding crushing or chewing.

#### **If you have accidentally taken a higher dosage**

If you have taken an overdose, if you experience one of the symptoms described above, or if a child has accidentally swallowed the medicine, proceed immediately to a doctor or a hospital emergency room and bring the package of the medicine with you.

If you have taken an overdose, you may experience any of the following symptoms: sleepiness or fatigue, or abnormal body movements, difficulty standing or walking, dizziness due to low blood pressure, abnormal heart rate or seizures.

#### **If you forgot to take this medicine**

If you forgot to take this medicine at the designated time, take it as soon as you remember. However, if it is almost time for your next dose - skip the forgotten dose and take the next dose at the regular time.

If you missed two or more doses, contact your doctor.

**Do not take a double dose to make up for a missed dose.**

Continue with treatment as recommended by the doctor.

Even if there is an improvement in your health, do not stop treatment with this medicine without consulting the doctor.

#### **If you stop taking the medicine**

Do not discontinue treatment with the medicine unless specifically told to do so by the doctor. Discontinuing treatment may cause the symptoms to return.

If the doctor decides to stop the treatment, the dosage should be gradually decreased over a few days according to the doctor's instructions.

**Do not take medicines in the dark! Check the label and the dose each time you take a medicine. Wear glasses if you need them.**

**If you have further questions on the use of this medicine, consult the doctor or pharmacist.**

#### **4. Side effects**

Like any medicine, the use of **Risperidex** 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.

**Refer to the doctor immediately if you experience any of these uncommon side effects** (effects that occur in 1-10 out of 1,000 users):

- You have dementia and you experience a sudden change in mental state or sudden weakness or numbness in the face, arms or legs, especially on one side, or slurred speech, even for a short period of time. These may be signs of stroke.
- You experience tardive dyskinesia (sudden or twitching uncontrollable movements in the face, tongue or other parts of the body). Tell your doctor immediately if you experience involuntary rhythmic movement of the tongue, mouth, or face. Treatment with **Risperidex** may need to be discontinued.

**Refer to the doctor immediately if you experience any of these rare side effects** (effects that occur in 1-10 out of 10,000 users):

- You experience blood clots in the veins, especially in the legs (symptoms include swelling, pain and redness in the legs), which may travel through the blood vessels to the lungs and cause chest pain and difficulties breathing. If you experience any of these symptoms, seek medical care immediately.
- You experience fever, muscle stiffness, sweating or decreased level of consciousness (a syndrome called Neuroleptic malignant syndrome). Immediate medical care may be needed.
- You are a man and experience a prolonged or painful erection, this phenomenon is called priapism. Immediate medical care may be needed.
- You experience a severe allergic reaction characterized by fever, swelling of the mouth, face, lips or tongue, shortness of breath, itching, skin rash or a drop in blood pressure.

#### **Additional side effects**

**Very Common side effects** (effects that occur in more than one out of ten users):

- Difficulty falling or staying asleep.
- Parkinsonism characterized by slow or impaired movement, a sensation of stiffness or tightness of the muscles (which causes jerky movement) and sometimes even a feeling of movement "freezing up" followed by restarting of the movement. Additional signs of Parkinsonism may include a slow shuffling walk, tremor during rest, increased saliva and/or drooling, and loss of facial expression.
- Sleepiness or decreased alertness.
- Headache.

**Common side effects** (effects that occur in 1-10 out of 100 users):

- Pneumonia, infection in the chest (bronchitis), cold symptoms, sinus infection, urinary tract inflammation, ear infection, a flu-like illness.
- Risperidone may cause raised levels of the prolactin hormone, as can be seen in blood tests (which may or may not cause symptoms). Symptoms of high prolactin rarely occur and may include in men, breast swelling, difficulty to achieve or maintain an erection, decreased sexual desire or other sexual dysfunction. In women, the symptoms may include a feeling of breast discomfort, secretion of milk from the breasts, lack of menstruation or other disorders of the menstrual cycle or fertility problems.
- Weight gain, increased appetite, decreased appetite.
- Sleep disorders, irritability, depression, anxiety, restlessness.
- Dystonia: this is a condition that involves a slow or sustained involuntary contraction of the muscles. While it can involve any part of the body (and may manifest in abnormal posture), it usually affects facial muscles. It includes abnormal movements of the eyes, mouth, tongue or the jaw.
- Dizziness.
- Dyskinesia: This is a condition involving involuntary muscle movements that can include repetitive, spastic or twisting movements or contractions.
- Tremor.
- Blurry vision, conjunctivitis ("pink eye").
- Rapid heart rate, high blood pressure, shortness of breath.
- Sore throat, cough, nosebleeds, stuffy nose.
- Abdominal pain, abdominal discomfort, vomiting, nausea, constipation, diarrhea, indigestion, dry mouth, toothache.
- Rash, skin redness.
- Muscle spasms, bone or muscle pain, back pain, joint pain.
- Urinary incontinence (loss of control).
- Swelling of the body, arms or legs, fever, chest pain, weakness, fatigue, pain.
- Falls.

**Uncommon side effects** (effects that occur in 1-10 out of 1,000 users):

- Infection of the respiratory tract, bladder infection, eye infection, tonsillitis, fungal infection of the nails, skin infection, infection confined to a single area of the skin or part of the body, viral infection, skin inflammation caused by mites.
- Decreased levels of white blood cells that help protect against infections, decreased white blood cell count, decreased platelet count (blood cells that help stop bleeding), anemia, decreased red blood cell levels, an increase in eosinophils (a type of white blood cells) in the blood.
- Allergic reaction.
- Diabetes or worsening of diabetes, high blood sugar level, excessive drinking of water.
- Weight loss, loss of appetite resulting in malnutrition and low body weight.
- Increased blood cholesterol level.
- Elated mood (mania), confusion, decreased libido, nervousness, nightmares.
- Lack of response to stimulation, loss of consciousness, low level of consciousness.
- Convulsions, fainting.
- A restless urge to move parts of the body, balance disorder, abnormal coordination, dizziness upon standing up, attention disorders, speech problems, loss or abnormal sense of taste, reduced sensation of the skin to pain and touch, tingling sensation, prickling or numbness of the skin.
- Oversensitivity of the eyes to light, dry eyes, increased tear secretion, redness of the eyes.
- Feeling dizzy (vertigo), ringing in the ears, earache.
- Atrial fibrillation (irregular heart rate), interruption in conduction between the upper and lower parts of the heart, abnormal electrical conduction of the heart, prolongation of the QT

interval of the heart, slow heart rate, abnormal electrical tracing of the heart (electrocardiogram - ECG), a feeling of abnormal heartbeat (palpitations).

- Low blood pressure, low blood pressure upon standing up (consequently, some people taking risperidone may feel weak, dizzy, or may faint when standing up or sitting up suddenly), flushing.
- Pneumonia caused by inhalation of food, lung congestion, congestion in the air pathways, crackly lung sounds, wheezing, voice disorder, breathing passage disorder.
- Stomach or intestinal infection, stool incontinence (inability to hold in), very hard stool, difficulty swallowing, excessive gas in the digestive system.
- Hives (skin rash), itching, hair loss, thickening of the skin, eczema, dry skin, skin discoloration, acne, dandruff and itching of the scalp or skin, skin problems, skin lesions.
- An increase of CPK (creatine phosphokinase) level in the blood, an enzyme that is sometimes released due to muscle breakdown.
- Abnormal position/posture, joint stiffness, joint swelling, muscle weakness, neck pain.
- Frequent urination, inability to urinate, pain during urination.
- Erectile dysfunction, ejaculation disorders.
- Lack of menstruation, late menstruation or any other menstrual cycle disorder (women).
- Development of breasts in men, secretion of milk from the breasts, sexual dysfunction, breast pain, breast discomfort, vaginal discharge.
- Swelling of the face, mouth, eyes, or lips.
- Chills, an increase in body temperature.
- A change in the way you walk.
- Feeling thirsty, general feeling of being unwell, chest discomfort, poor mood, discomfort.
- Increased liver transaminase levels in the blood, increased GGT level (a liver enzyme called gamma-glutamyl transferase) in the blood, increased liver enzyme levels in the blood.
- Pain during medical treatment.

**Rare side effects** (effects that occur in 1-10 out of 10,000 users):

- Infection.
- Inappropriate secretion of a hormone that regulates urine volume.
- Sleepwalking.
- Sleep-related eating disorder.
- The presence of sugar in the urine, low blood sugar level, high blood triglycerides (fats) level.
- Lack of emotion, inability to reach sexual satisfaction (orgasm).
- Not moving or responding while awake (catatonia).
- Blood vessel problems in the brain.
- Coma due to uncontrolled diabetes.
- Shaking of the head.
- Glaucoma (high pressure within the eye), eye movement disorders, eye rolling, eyelid margin crusting.
- Eye problems during cataract surgery. During cataract surgery, a condition called intraoperative floppy iris syndrome (IFIS) may occur if you are taking or have taken risperidone. If you need to have a cataract surgery, tell the doctor if you are taking or have taken risperidone.
- Dangerously low numbers of a certain type of white blood cell in your blood needed to fight infections.
- Dangerously excessive intake of water.
- Irregular heartbeat.
- Difficulty breathing (apnea) during sleep, fast and shallow breathing.
- Pancreas inflammation, bowel obstruction.
- Swollen tongue, chapped lips, skin rash related to a medication.
- Dandruff
- Breakdown of muscle fibers and muscle pain (rhabdomyolysis).

- Delayed menstruation, enlargement of the breast glands, breast enlargement, secretion from the breasts.
- Increased blood insulin (a hormone that controls blood sugar levels).
- Hardening of the skin.
- Decreased body temperature, cold sensation in the arms and legs.
- Symptoms of drug withdrawal.
- Yellowing of the skin and eyes (jaundice).

**Very rare side effects** (effects that occur in less than 1 out of 10,000 users):

- Life threatening complications due to uncontrolled diabetes.
- A severe allergic reaction with swelling that can involve the throat and lead to breathing difficulties.
- Lack of muscle movement in the digestive system that causes blockage.

**Side effects with unknown frequency** (effects for which a frequency has not yet been determined):

Severe or life-threatening rash, with blisters and peeling skin which may begin inside and around the mouth, nose, eyes and genitals and spread to other areas of the body (Stevens-Johnson syndrome or toxic epidermal necrolysis - TEN).

The following side effect has been observed with the use of another medicine called paliperidone, a medicine that is very similar to risperidone, and may therefore also occur with risperidone: rapid heartbeat upon standing up.

#### **Additional side effects in children and adolescents:**

In general, side effects in children are expected to be similar to those in adults.

Side effects reported in clinical studies in children and adolescents:

Tardive dyskinesia (sudden or twitching uncontrollable movements in the face, tongue or other parts of the body), weight gain, sleepiness, high blood prolactin levels, milk secretion from the breasts, breast enlargement in children and adolescents (gynecomastia), increased blood sugar levels, increased blood lipid levels.

Increased saliva secretion, parkinsonism, akathisia (physical restlessness), dystonia, anxiety have also been reported.

The following side effects were reported more often in children and adolescents (5 to 17 years) than in adults: sleepiness or decreased alertness, fatigue (tiredness), headache, increased appetite, vomiting, common cold symptoms, nasal congestion, abdominal pain, dizziness, cough, fever, tremor, diarrhea and urinary incontinence.

**If a side effect occurs, if one of the side effects worsens or if you suffer from a side effect which is not mentioned in this leaflet, consult the doctor.**

Side effects can be reported to the Ministry of Health via the link

"דיווח על תופעות לוואי עקב טיפול תרופתי" found on the homepage of the Ministry of Health website ([www.health.gov.il](http://www.health.gov.il)) directing to the online form for reporting side effects, or via the link: <https://sideeffects.health.gov.il>

#### **5. How to store the medicine?**

- Avoid poisoning! This medicine and any other medicine must be stored in a closed 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 (תאריך תפוגה) stated on the package. The expiry date refers to the last day of that month.
- **Storage conditions:** Store below 25°C.



- Do not throw away any medicines via wastewater or household waste. Ask the pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

## **6. Additional information**

### **In addition to the active ingredient, this medicine also contains:**

Lactose monohydrate, maize starch, microcrystalline cellulose, povidone, hypromellose, titanium dioxide (E171), magnesium stearate, silica colloidal anhydrous, macrogol, sodium laurilsulfate, carnauba wax.

### **What the medicine looks like and what the package contains:**

**Risperidex 1mg:** white round tablets scored on one side.

**Risperidex 2mg:** white caplets.

**Risperidex 3mg:** white round tablets.

**Risperidex 4mg:** white caplets.

Approved package sizes: 20, 30. Not all package sizes may be marketed.

**Manufacturer name and address:** Dexcel Ltd., 1 Dexcel St., Or Akiva 3060000, Israel

Revised in October 2023 according to MOH guidelines.

### **Drug registration numbers at the national drug registry of the Ministry of Health:**

**Risperidex 1 mg:** 134 54 31353 00

**Risperidex 2 mg:** 134 55 31354 00

**Risperidex 3 mg:** 134 56 31355 00

**Risperidex 4 mg:** 134 57 31356 00

**Registration holder:** Dexcel Pharma Technologies Ltd.  
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