

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

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

Risperidex® 1mg, 3mg, Tablets

Risperidex® 2mg, 4mg, Caplets

Each tablet/caplet contains risperidone at a dosage of 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.
- For the treatment of mania in bipolar disorder.
- 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.
- For long-term treatment in order to maintain improvement in the condition of the illness in patients who have shown an initial response.
- For the treatment of behavioral disorders such as violence, impulsiveness and self-alienated-aggressive behavior in children above 5 years of age and adolescents with reduced or substandard intelligence.

Therapeutic group: antipsychotics medicine.

Schizophrenia - a condition where the patient can see or feel things that are not there, believe things that are not true or feel unusually suspicious or confused, and symptoms of psychotic disorders. Mania - A condition where 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 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 you are prone to low blood pressure or 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's disease 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 epilepsies.
- You are a man and have suffered from a prolonged or painful erection in the past.
- 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 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 white blood cells needed to protect against infections has been rarely observed in patients taking a risperidone-containing medicine, your doctor may check your white blood cell counts.
- **Risperidex** 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 has been observed in patients taking a risperidone-containing medicine, your doctor will check for signs of high blood sugar levels. In patients with pre-existing diabetes, blood glucose levels should be monitored regularly.
- **Risperidex** 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 turbidity of the eye lens) the pupil of the eye (the black circle in the center of the eye) may not grow to the desired size. Also, the iris (the colored part of the eye) may become loose during surgery and this may cause eye damage. If you are planning to have an eye surgery, tell your eye doctor that you are taking or have taken this medicine.

Elderly patients 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 a doctor. You should seek immediate medical help if you or your care-giver notices a sudden change in your mental state or sudden weakness or loss of feeling/sudden numbness 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 commencing treatment for behavioral problems, 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 commencing 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 growth in children who have taken risperidone. But whether this effect was caused by the medicine or by some other reason is unknown.

Drug interactions

If you are taking, or if you have recently taken, any other medicines including non-prescription drugs and dietary 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 **Risperidex** 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. **Risperidex** may lower blood pressure.
- Medicines for the treatment of Parkinson's disease (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). **Risperidex** 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 problems).

- 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 **Risperidex**.

Use of this medicine and food

The medicine can be taken with or without food. **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.

Pregnancy, breastfeeding and fertility

- If you are pregnant, breastfeeding, think you may be pregnant or are planning to have a baby, consult your doctor who will decide if you can take **Risperidex**.
- The following symptoms may occur in newborn babies of mothers who have used **Risperidex** in the last trimester (last three months of their pregnancy): Tremor, muscle stiffness and/or weakness, sleepiness, restlessness, breathing problems or eating difficulties. If your baby develops any of these symptoms you may need to inform your doctor.
- **Risperidex** 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 fatigue, dizziness and vision problems, therefore do not drive a vehicle, operate machinery or tools without first consulting your doctor. Children should be cautioned against riding bicycles or playing near the road etc.

Important information about some of the ingredients of this 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.

3. How to use this medicine

Always use this medicine as instructed by the doctor.

Check with the doctor or pharmacist if you are unsure about the dosage and the manner of treatment with the medicine.

The dosage and administration 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:

Risperidex can be taken with or in between meals.

Method of administration: Swallow the medicine with a glass of 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, you may experience one 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 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 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 a doctor. Discontinuing treatment may cause the symptoms to return.

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

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 all medicines, 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 one of these uncommon side effects (effects that appear 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 movements or uncontrollable spasms of the face, tongue or other parts of the body). Tell your doctor 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 one of these rare side effects (effects that appear 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 in breathing. If you experience one of these symptoms immediately seek medical care.
- 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.

Uncommon side effects (effects that appear 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, a low 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.
- Contractions, fainting.
- A restless urge to move parts of the body, disturbances in balance, coordination impairment, dizziness upon

Very Common side effects (effects that appear 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 distortions in movement) and sometimes even a feeling of stagnation in movement accompanied by subsequent 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 which appear in 1-10 out of 100 users):

- Pneumonia, inflammation of the bronchial tubes (bronchitis), cold symptoms, sinus infection, urinary tract infection, ear infection, a flu-like illness.

- Risperidex 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, swelling of the breasts, difficulty to achieve or maintain an erection, decreased sexual desire or other sexual dysfunction.

In women, the symptoms may include: a feeling of discomfort in the breasts, 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 prolonged involuntary contraction of the muscles. While it can involve any part of the body (and may be manifested in abnormal posture), it usually affects facial muscles, including abnormal movements of the eyes, mouth, tongue or jaw.
- Dizziness.
- Dyskinesia: This is a condition that involves involuntary muscle movements that can include repetitive movements or spastic or twisting 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, redness of the skin.
- Muscle spasms, bone or muscle ache, back pain, joint pain.
- Urinary incontinence (involuntary leakage of urine).
- Swelling of the body, arms or legs, fever, chest pain, weakness, fatigue, pain.
- Falls.

Uncommon side effects (effects that appear 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, a low 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.
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- 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.
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standing, attention disorders, speech problems, loss or abnormal sense of taste, reduced sensation of skin to pain and touch, tingling sensation, stinging 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), obstruction in the conduction between the upper and lower parts of the heart, abnormal electrical conduction of the heart, extension of the heart's QT interval, slow heart rate, abnormal electrical heartbeat test (electrocardiogram -ECG), a feeling of abnormal heartbeat (palpitations).
- Low blood pressure, low blood pressure upon standing (consequently, some people taking Risperidex may feel weak, dizzy, or may faint when standing or sitting suddenly), flushing.
- Pneumonia caused by inhalation of food, congestion in the lungs, congestion in the airways, rustling sound from the lungs, wheezing, voice disturbance, respiratory disturbance.
- Stomach or intestinal infection, fecal incontinence (the inability to control bowel movements), very hard stool, difficulty in swallowing, excessive passing of gas in the digestive system.

- 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) 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 appear in less than one out of 10,000 users):

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

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

Additional side effects in children and adolescents: In general, side effects in children are expected to be similar to those in adults. 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, cold symptoms, nasal congestion, abdominal pain, dizziness, cough, fever, tremor, diarrhea and urinary incontinence.

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

- Infection.
- Improper secretion of the hormone that regulates urine volume.
- Sleepwalking.
- Eating disorders related to sleep.
- The presence of sugar in the urine, low blood sugar level, high blood triglycerides (fats) level.
- Lack of emotion, inability to achieve an 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 intraocular pressure), 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 **Risperidex**. If you need to have cataract surgery, tell your eye doctor if you are taking or have taken **Risperidex**.
- Dangerously low numbers of a certain type of white blood cell needed to fight infection in your blood.
- Excessive intake of water that endangers the body.
- Irregular heartbeat.
- Difficulty breathing (inability to breathe) during sleep, rapid, shallow breathing.
- Inflammation of the pancreas, bowel obstruction.
- Swollen tongue, chapped lips, rash on the skin as a result of 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) levels.
- Hardening of the skin.
- Decreased body temperature, cold sensation in the arms and legs.
- Symptoms of drug withdrawal.
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Very rare side effects (effects that appear in less than one out of 10,000 users):

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Common side effects (effects which appear in 1-10 out of 100 users):

- Pneumonia, inflammation of the bronchial tubes (bronchitis), cold symptoms, sinus infection, urinary tract infection, ear infection, a flu-like illness.

- Parkinsonism characterized by: slow or impaired movement, a sensation of stiffness or tightness of the muscles (which causes distortions in movement) and sometimes even a feeling of stagnation in movement accompanied by subsequent movement. Additional signs of Parkinsonism may include: a slow shuffling walk, tremor during rest, increased saliva and/or drooling, and loss of facial expression.
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effect which is not mentioned in this leaflet, consult the doctor.

Reporting of side effects:

Side effects that are reported to the Ministry of Health via the link "עזרה טיפולית" "עזרה טיפולית" "עזרה טיפולית" that can be found on the home page of the Ministry of Health website (www.health.gov.il) directing to the online form of adverse events reporting or via the following link: <https://sideeffects.health.gov.il/>

5. How to store this 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 your 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:** Do not store at a temperature above 25°C.

6. Additional information

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

Lactose monohydrate, Maize starch, Microcrystalline cellulose, Povidone, Hypromellose, Titanium dioxide, 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: 2, 5, 7, 10, 14, 20, 21, 28, 30, 100.

Not all package sizes may be marketed.

Manufacturer's address: Dexcel Ltd., 1 Dexcel St., Or Akiva 3060000, Israel
Revised in August 2020.

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

Risperidex tablets & caplets PIL PB1020-06

Registration holder:
Dexcel Pharma Technologies Ltd.

1 Dexcel St., Or Akiva 3060000, Israel