

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

The medicine is dispensed with a doctor's prescription only

Risperdal® 1 mg, Film-coated Tablets

Risperdal® 2 mg, Film-coated Tablets

Risperdal® 3 mg, Film-coated Tablets

Risperdal® 4 mg, Film-coated Tablets

Risperdal® 1 mg/ml Oral Solution

Active ingredient and its amount:

Risperdal 1 mg film-coated tablets contain: Risperidone 1 mg

Risperdal 2 mg film-coated tablets contain: Risperidone 2 mg

Risperdal 3 mg film-coated tablets contain: Risperidone 3 mg

Risperdal 4 mg film-coated tablets contain: Risperidone 4 mg

Each 1 ml oral solution contains: Risperidone 1 mg

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 this 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 illness is similar.

1. WHAT IS THE MEDICINE INTENDED FOR?

- Risperdal is intended for the treatment of schizophrenia and symptoms of psychotic disorders.
- Risperdal is also effective in maintaining the clinical improvement in long-term treatment in patients who have exhibited an initial response to treatment.
- Risperdal is intended for the treatment of psychotic manifestations of moderate to severe Alzheimer's dementia (short-term treatment up to six weeks in cases of consistent aggression) in patients who are not responding to non-pharmacological treatments and in whom there is concern that they will harm themselves or others.

Additional behavioral disorders:

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

- For treatment of state of mania in bipolar disorder.

Therapeutic group: anti-psychotic preparation

Risperdal can help alleviate the symptoms of the disease and stop them from coming back.

Schizophrenia – a condition in which the patient can see or feel things that are not there, believe 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, elated, agitated, enthusiastic or hyperactive.

2. BEFORE USING THE MEDICINE

Do not use the medicine if:

you are sensitive (allergic) to risperidone or to any of the other ingredients contained in the medicine. For the list of additional ingredients, see section 6 “Further information”.

Special warnings regarding use of the medicine

Before treatment with Risperdal, inform the doctor if:

- you have a heart problem. Examples include an irregular heart rhythm or if you are prone to low blood pressure or you are using medicines for your blood pressure. Risperdal may cause low blood pressure. Your dose may need to be adjusted
- you know of any factors which would favor you having a stroke, such as, high blood pressure, cardiovascular disorder or blood vessel problems in the brain
- you have ever experienced involuntary movements of the tongue, mouth and face
- you have ever had a condition whose symptoms include high temperature, muscle stiffness, sweating or a lowered level of consciousness (also known as Neuroleptic Malignant Syndrome)
- you have Parkinson’s disease or dementia
- you know that you have had low levels of white blood cells in the past (which may, or may not, have been caused by other medicines)
- you have diabetes
- you have epilepsy
- you are a man and you have ever had a prolonged or painful erection
- you have problems controlling your body temperature or overheating
- you have kidney problems
- you have liver problems
- you have an abnormally high level of the prolactin hormone in your blood or if you have a possible prolactin-dependent tumor
- you or someone else in your family has a history of blood clots, as antipsychotics have been associated with formation of blood clots

If you are not sure if any of the above applies to you, talk to your doctor or pharmacist before using Risperdal.

As dangerously low numbers of a certain type of white blood cell needed to fight

infection in your blood has been seen very rarely with patients taking Risperdal, your doctor may check your white blood cell counts.

Risperdal may cause you to gain weight. Significant weight gain may adversely affect your health. Your doctor should regularly measure your body weight.

As diabetes mellitus or worsening of pre-existing diabetes mellitus have been seen with patients taking Risperdal, your doctor should check for signs of high blood sugar. In patients with pre-existing diabetes mellitus blood sugar should be monitored regularly.

Risperdal commonly raises levels of the prolactin hormone. This may cause side effects such as menstrual disorders or fertility problems in women, breast swelling in men (see section 4 "Side effects"). If such side effects occur, evaluation of the prolactin level in the blood is recommended.

During cataract (an eye disease manifested by cloudiness of the lens) surgery, the pupil (the black circle in the middle of the eye) may not increase in size as needed. Also, the iris (the colored part of the eye) may become floppy during surgery, which may lead to eye damage. If you are planning to have an operation on your eye, 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. Do not take Risperdal if you have dementia caused by stroke.

During treatment with risperidone, you should frequently see your doctor.

Medical treatment should be sought straight away if you or your caregiver notice a sudden change in your mental state or sudden weakness or numbness of your 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 Risperdal tiredness occurs, a change in the time of administration of the medicine might improve attention difficulties.

Before starting treatment, weigh the child or adolescent and regularly monitor weight throughout the course of treatment.

A small and inconclusive study has reported an increase in height in children who took risperidone, but whether this is an effect of the drug or due to some other reason is not known.

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

Drug interactions

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

- Medicines that work on your brain such as to help you calm down

- (benzodiazepines), or some medicines for pain (opiates), medicines for allergy (some antihistamines), as Risperdal may increase the sedative effect of all of these.
- Medicines that may change the electrical activity of the heart, such as medicines for malaria, medicines for heart rhythm problems, medicines for allergies (antihistamines), some 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 to treat raised blood pressure. Risperdal can lower blood pressure.
 - Medicines for Parkinson's disease (such as levodopa).
 - Medicines that increase the activity of the central nervous system (psychostimulants, such as methylphenidate).
 - Water tablets (diuretics) used for heart problems or swelling of parts of your body due to a build-up of too much fluid (such as furosemide or chlorothiazide). Risperdal taken by itself or with furosemide, may have an increased risk of stroke or death in elderly patients with dementia.

The following medicines may reduce the effect of risperidone:

- Rifampicin (a medicine for treating certain infections)
- Carbamazepine, phenytoin (medicines for treating 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 to treat certain types of heart disease)
- Antidepressants such as paroxetine, fluoxetine, tricyclic antidepressants
- Beta blockers (to treat hypertension)
- Phenothiazines (such as medicines used to treat psychosis or to calm down)
- Cimetidine, ranitidine (medicines to lower stomach acidity)
- Itraconazole and ketoconazole (to treat fungal infections)
- Certain medicines to treat HIV/AIDS, such as ritonavir
- Verapamil, to treat high blood pressure and/or abnormal heart rhythm
- Sertraline and fluvoxamine, to treat depression and other psychiatric disorders

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

If you are uncertain about any of the points above, refer to a doctor or pharmacist before taking Risperdal.

Use of the medicine and food

Risperdal can be taken with or without food.

Risperdal use and alcohol consumption

You should avoid drinking alcohol when taking Risperdal.

Pregnancy, breastfeeding and fertility

- If you are pregnant or breastfeeding, think you may be pregnant or are planning to

have a baby, ask your doctor for advice before taking the medicine. Your doctor will decide if you can take Risperdal.

- The following symptoms may occur in babies, of mothers that have used Risperdal in the last trimester of pregnancy (the last three months of pregnancy): shaking, muscle stiffness and/or weakness, sleepiness, agitation, breathing problems, and difficulty in feeding. If your baby develops any of these symptoms, you may need to contact the doctor.
- Risperdal can raise the levels of a hormone called prolactin, which may impact fertility (see section 4 “Side effects”).

Driving and using machines

Use of this medicine may cause dizziness, tiredness and vision problems. Therefore, do not drive or use any machines or tools without talking to your doctor first.

Important information regarding some of the ingredients of the medicine

Risperdal tablets contain a type of sugar called lactose. If you have an intolerance to some sugars, consult the doctor before taking Risperdal tablets.

Risperdal tablets and Risperdal oral solution contain less than 1 mmol (23 mg) sodium per dose, therefore, they are considered essentially 'sodium-free'.

Risperdal 2 mg tablets contain orange yellow (sunset yellow E110) which may cause allergic reactions.

Risperdal Oral Solution contains benzoic acid (E210). The medicine contains 2 mg benzoic acid per 1 ml oral solution.

3. HOW SHOULD THE MEDICINE BE USED?

Always take this medicine exactly as your doctor has told you.

Check with the doctor or pharmacist if you are uncertain regarding the dosage and treatment regimen of the preparation.

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

After administration of the first dose, the doctor may gradually adjust the dosage of the medicine for you, depending on your reaction to treatment.

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

In elderly patients, use a lower dosage of Risperdal, as per the doctor's instructions.

Patients suffering from liver or kidney problems: these patients should take a lower dose of Risperdal, as per the doctor's instructions. Use Risperdal with caution in these patients.

Do not exceed the recommended dose.

Directions for use:

Risperdal can be taken with or between meals.

Use of Risperdal Tablets

Swallow the tablet with water.

There is no information regarding crushing and chewing the tablets. The tablet can be halved on the marked score line. The score line is intended to assist in splitting the tablet if it is difficult to swallow it whole, but both parts have to be taken together

immediately after splitting.

Use of Risperdal Oral solution

Mix the oral solution with any beverage that does not contain alcohol, except for tea. The solution is provided with a measuring syringe. Use the measuring syringe to measure the exact amount.

Follow the instructions below:

Figure 1: To open the child-proof cap, press down while turning counterclockwise.

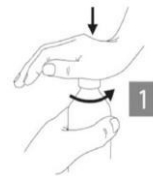


Figure 2: Insert the measuring syringe into the bottle.



Figure 3: Hold the bottom ring, pull the top ring up to the mark that corresponds to the number of milliliters or milligrams that you need to take.

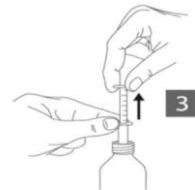
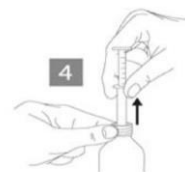


Figure 4: While holding the bottom ring, remove the measuring syringe from the bottle. Empty the syringe into any non-alcoholic beverage (except for tea), by pressing down on the upper ring.

Close the bottle and rinse the measuring syringe with water.



If you accidentally take a higher dosage

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

If you took an overdose, you may experience any of the following symptoms: feel sleepy or tired, or have abnormal body movements, problems standing and walking, feel dizzy due to low blood pressure, have abnormal heartbeats or fits.

If you forget to take Risperdal

If you forgot to take the medicine, take it as soon as you remember. However, if it is almost time to take the next dose – skip the missed dose and take the next dose on time.

If you miss two or more doses, contact the doctor.

Do not take a double dose to compensate for a forgotten dose.

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 the doctor.

If you stop taking the medicine

Do not discontinue treatment with the medicine unless your doctor has explicitly instructed you to do so. Discontinuation of treatment may lead to recurrence of the disease symptoms. If the doctor instructs to stop treatment, your dose may be decreased gradually over a few days, as per 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 Risperdal may cause side effects in some users. Do not be alarmed by the list of side effects. You may not suffer from any of them.

Refer to a doctor immediately if you experience any of the following uncommon side effects – effects that occur in up to 1 in 100 users

- you have dementia and you experience a sudden change in your mental state or sudden weakness or numbness of 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.
- you experience tardive dyskinesia (twitching or jerking movements that you cannot control in your face, tongue, or other parts of your body). Tell the doctor immediately if you experience involuntary rhythmic movements of the tongue, mouth or face. The treatment with Risperdal may have to be terminated.

Refer to a doctor immediately if you experience any of the following rare side effects – effects that occur in up to 1 in 1,000 users

- you experience blood clots in the veins, especially in the legs (the symptoms include swelling, pain, and redness in the leg), which may travel through blood vessels to the lungs, causing chest pain and difficulty breathing. If you notice any of these symptoms seek medical advice immediately.
- you experience fever, muscle stiffness, sweating or a lowered level of consciousness (a disorder called Neuroleptic Malignant Syndrome). Immediate medical treatment may be needed.
- you are a man and experience a prolonged and painful erection. This is called

priapism. Immediate medical treatment 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 1 in 10 users

- Difficulty falling or staying asleep.
- Parkinsonism manifested by impaired or slow movement, sensation of muscle stiffness or tightness (which cause jerky movements) and sometimes even a sensation of movement “freezing up”, followed by restarting of the movement. Other signs of Parkinsonism can include a slow shuffling walk, tremor while at rest, increased saliva and/or drooling, and a loss of expression on the face.
- Feeling sleepy, or less alert.
- Headache.

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

- Pneumonia, infection in the chest (bronchitis), common cold symptoms, sinus infection, urinary tract infection, ear infection, flu-like illness.
- Risperdal can cause elevated levels of the prolactin hormone, which can be detected in blood tests (that may, but not necessarily, cause symptoms). Symptoms of high prolactin occur uncommonly and may include in men breast swelling, difficulty in getting or maintaining erections, decreased sexual desire or other sexual dysfunction. In women, the symptoms may include breast discomfort, leakage of milk from the breasts, missed menstrual periods, or other problems with your cycle or fertility problems.
- Weight gain, increased appetite, decreased appetite.
- Sleep disorders, irritability, depression, anxiety, restlessness.
- Dystonia: this is a condition involving slow or sustained involuntary contraction of muscles. While it can involve any part of the body (and may result in abnormal posture), dystonia often involves muscles of the face, including abnormal movements of the eyes, mouth, tongue or jaw.
- Dizziness.
- Dyskinesia: this is a condition involving involuntary muscle movements, which can include repetitive, spastic or writhing movements, or twitching.
- Tremor.
- Blurry vision, eye infection or conjunctivitis.
- Rapid heart rate, high blood pressure, shortness of breath.
- Sore throat, cough, nosebleed, 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.
- Incontinence (lack of control) of urine.

- Swelling of the body, arms or legs, fever, chest pain, weakness, fatigue, pain.
- Fall.

Uncommon side effects – effects that occur in up to 1 in 100 users

- Infection of the respiratory passages, bladder infection, eye infection, tonsillitis, fungal infection of the nails, infection of the skin, infection confined to a single area of skin or part of the body, viral infection, skin inflammation caused by mites.
- Decrease in the level of white blood cells that help protect against infections, white blood cell count decrease, decrease in platelet level (blood cells that help stop bleeding), anemia, decrease in the level of red blood cells, increase in eosinophils (a type of white blood cell) 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 level of cholesterol in the blood.
- Elated mood (mania), confusion, decreased sexual drive, irritability, nightmares.
- Unresponsiveness to stimuli, loss of consciousness, low level of consciousness.
- Convulsions, fainting.
- A restless urge to move parts of the body, balance disorders, abnormal coordination, dizziness upon standing up, disturbance in attention, problems with speech, loss or abnormal sense of taste, reduced sensation of the skin to pain and touch, a sensation of tingling, prickling, or numbness of the skin.
- Oversensitivity of the eyes to light, dry eyes, increased tears, redness of the eyes.
- Sensation of spinning (vertigo), ringing in the ears, ear pain.
- Atrial fibrillation (irregular heart rhythm), an 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 test of electrical tracing of the heart (electrocardiogram or ECG), feeling of abnormal heartbeats (palpitations).
- Low blood pressure, low blood pressure upon standing up (consequently, some people taking Risperdal may feel weak, dizzy or may faint when suddenly transitioning to a standing or sitting position), flushing.
- Pneumonia caused by inhaling food, lung congestion, congestion of breathing passages, crackly lung sounds, wheezing, voice disorder, breathing passage disorder.
- Stomach or intestinal infection, stool incontinence (inability to hold in), very hard stools, 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 disorder, skin lesion.
- An increase of CPK levels (creatine phosphokinase) in the blood, an enzyme which is sometimes released due to muscle breakdown.
- Abnormal posture/body position, joint stiffness, joint swelling, muscle weakness,

neck pain.

- Frequent passing of urine, inability to pass urine, pain when passing urine.
- Erectile dysfunction, ejaculation disorders.
- Loss of menstrual periods, missed menstrual periods or other problems with your cycle (females).
- Development of breasts in men, leakage 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 unwell feeling, chest discomfort, feeling “out of sorts”, 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.
- Procedural pain.

Rare side effects – effects that occur in up to 1 in 1,000 users

- Infection.
- Inappropriate secretion of a hormone that controls urine volume.
- Sleep walking.
- Sleep-related eating disorder.
- Presence of sugar in the urine, low blood sugar level, high blood triglycerides (fat).
- Lack of emotion, inability to reach sexual satisfaction (orgasm).
- Not moving or responding while awake (catatonia).
- Problems with blood vessels in the brain.
- Coma due to uncontrolled diabetes.
- Shaking of the head.
- Glaucoma (increased pressure within the eyeball), problems with movement of your eyes, 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 Risperdal. If you need to have cataract surgery, tell your doctor if you are taking or have taken Risperdal.
- Dangerously low numbers of certain type of white blood cell needed to fight infection in your blood.
- Dangerously excessive intake of water.
- Irregular heart rate.
- Trouble breathing during sleep (sleep apnea), rapid and shallow breathing.
- Inflammation of the pancreas, a blockage in the bowels.
- Swollen tongue, chapped lips, drug-related skin rash.
- Dandruff.
- Breakdown of muscle fibers and muscle pain (rhabdomyolysis).
- A delay in menstrual period, enlargement of the glands in the breasts, breast

enlargement, discharge from the breasts.

- Increased blood insulin (a hormone that regulates the sugar levels in the blood).
- Hardening of the skin.
- Decreased body temperature, coldness in arms and legs.
- Symptoms of drug withdrawal.
- Yellowing of the skin and the eyes (jaundice).

Very rare side effects – effects that occur in up to 1 in 10,000 users

- Life threatening complications of uncontrolled diabetes.
- Serious allergic reaction with swelling that may involve the throat and lead to difficulty breathing.
- Lack of bowel muscle movement that causes blockage.

Side effects of unknown frequency – the frequency cannot be estimated from the available data:

Severe or life-threatening rash with blisters and peeling skin that may start in 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 seen with the use of another medicine called paliperidone, a medicine that is very similar to risperidone, and therefore, may also occur when using Risperdal: 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 uncontrollable jerking or twitching movements in the face, tongue or other parts of the body), weight gain, somnolence, high blood prolactin levels, leakage of milk from the breasts, breast enlargement in children and adolescents (gynecomastia), increased blood sugar level, increased blood lipid levels. In addition, increased excretion of saliva, parkinsonism, akathisia (physical unrest), dystonia and anxiety have been reported.

The following side effects were reported more often in children and adolescents (5 to 17 years) than in adults:

Feeling sleepy or less alert, fatigue (tiredness), headache, increased appetite, vomiting, common cold symptoms, nasal congestion, abdominal pain, dizziness, cough, fever, tremor, diarrhea, and incontinence (lack of control) of urine.

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, should be kept in a safe place out of the reach and sight of children and/or infants in order to avoid poisoning. Do not induce vomiting unless explicitly instructed to do so by the doctor.

Do not use the medicine after the expiry date (exp. Date) that appears on the package. The expiry date refers to the last day of that month.

Store at a temperature below 30°C.

Oral solution: Do not freeze.

Once the bottle is opened, it can be used for 3 months.

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer used. These measures will help to protect the environment.

6. FURTHER INFORMATION

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

Risperdal film-coated tablets:

Tablet core:

Lactose monohydrate, maize starch, microcrystalline cellulose, hypromellose 2910 15 mPa.s, magnesium stearate, colloidal anhydrous silica, sodium lauryl sulfate.

Film-coating:

Risperdal 1 mg:

Hypromellose 2910 5 mPa.s, propylene glycol.

Risperdal 2 mg:

Hypromellose 2910 5 mPa.s, titanium dioxide (E171), talc, propylene glycol, orange yellow S (E110) aluminum lake (sunset yellow).

Risperdal 3 mg:

Hypromellose 2910 5 mPa.s, titanium dioxide (E171), talc, propylene glycol, quinoline yellow (E104).

Risperdal 4 mg:

Hypromellose 2910 5 mPa.s, titanium dioxide (E171), talc, propylene glycol, quinoline yellow (E104), indigotindisulphonate (E132) aluminum lake.

Risperdal Oral Solution:

Tartaric acid, benzoic acid, sodium hydroxide, purified water.

What the medicine looks like and the contents of the pack

- Risperdal tablets: The tablets are packaged in blister packs containing 10 tablets each. The blister packs are packaged in a carton containing 20 tablets.

Risperdal 1 mg tablets: Film-coated, white, oblong, biconvex, half-scored tablet with the inscription **RIS|1** on one side.

Risperdal 2 mg tablets: Film-coated, slightly orange, oblong, biconvex, half-scored tablet with the inscription **RIS|2** on one side.

Risperdal 3 mg tablets: Film-coated, yellow, oblong, biconvex, half-scored tablet with the inscription **RIS|3** on one side.

Risperdal 4 mg tablets: Film-coated, green, oblong, biconvex, half-scored tablet with the inscription **RIS|4** on one side.

- Risperdal 1 mg/ml oral solution – the preparation comes in a 30 ml glass bottle with a child-proof cap. The carton package contains the preparation bottle and a measuring syringe. The solution is clear and colorless.

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

Manufacturer: Janssen Cilag S.p.A., Via C. Janssen, Borgo S.Michele, 04100, Latina, Italy.

Registration number of the medicine in the National Drug Registry of the Ministry of Health:

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|---------------------------------|---------------|
| Risperdal 1 mg tablets | 1447828260-01 |
| Risperdal 2 mg tablets | 1447928261-01 |
| Risperdal 3 mg tablets | 1448028262-01 |
| Risperdal 4 mg tablets | 1448128263-01 |
| Risperdal 1 mg/ml oral solution | 1147429633-00 |

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