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 Tablets contain: Risperidone 1 mg Risperdal 2 mg Tablets contain: Risperidone 2 mg Risperidone 3 mg Risperdal 3 mg Tablets contain: Risperdal 4 mg 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 ailment is similar.

1. WHAT IS THE MEDICINE INTENDED FOR?

- For the treatment of schizophrenia and symptoms of psychotic
- For treatment of state of mania in bipolar disorder
- 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
- For long-term treatment in order to maintain the improvement in the state of the illness in patients who have exhibited an initial response.
- 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.

Therapeutic group: anti-psychotic preparation

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 have a known sensitivity (allergy) 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. For example, irregular heart rhythm or you tend to have low blood pressure or you are taking medicines for your blood pressure. Risperdal may cause low

- blood pressure. Your dosage may have to be altered you have risk factors for stroke, for example, high blood pressure, cardiovascular disorders or cerebrovascular problems
- you have ever suffered from involuntary movements of the tongue, mouth or face
- you have ever had a condition whose symptoms include high fever, muscle stiffness, sweating or a decrease in 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, but not necessarily, have been caused by use of other medicines)
- you have epilepsy
- you are a man and you have ever had a prolonged or painful erection
- you suffer from difficulty regulating body temperature or from overheating
- you have kidney problems
- vou have liver problems
- you have abnormally high levels of the prolactin hormone in your blood or you have a prolactin-dependent tumor
- you suffer from the formation of blood clots or you have a family history of formation 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.

In very rare cases, dangerously low numbers of a type of white blood cells needed to protect against infection have been observed in patients taking Risperdal. Your doctor may check your white blood cell count.

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

Since diabetes mellitus or worsening of pre-existing diabetes mellitus has been seen in patients taking Risperdal, your doctor will check for signs indicating high blood sugar levels. In patients with pre-existing diabetes mellitus, blood glucose should be monitored regularly.

Risperdal commonly raises levels of the prolactin hormone. This may cause side effects such as menstrual problems 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 to the desired size. Likewise, 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 your doctor that you are taking this

■ Elderly patients with dementia

In elderly patients with dementia, there is an increased risk of stroke. Do not take Risperdal if you have dementia as a result of a stroke

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

Seek medical treatment 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 use to treat behavioral problems, 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 problems.

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. However, it is not known, if this effect is due to the medicine or for some other reason.

■ 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 it you are taking:

- Medicines that affect the brain e.g., sedatives (benzodiazepines), or certain pain-killers (opiates), anti-allergics (certain antihistamines), as Risperdal may increase the effect of the sedative effect of all 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 Medicines to treat hypertension. Risperdal may 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). Diuretics to treat heart problems or swelling of parts of the body due to excess build-up of fluid (such as: furosemide or chlorothiazide). Risperdal taken by itself or in combination with furosemide, may increase the risk of stroke or death in elderly patients with dementia.

The following medicines may reduce the effect of

- 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

- Quinidine (a medicine to treat certain types of heart problems) - Antidepressants such as paroxetine, fluoxetine, tricyclic
- antidepressants
- Beta blockers (to treat hypertension) - Phenothiazines (such as medicines used to treat psychosis or
- as tranquilizers) · 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
- 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

Abstain from drinking alcohol during the course of treatment

■ Pregnancy, breastfeeding and fertility

- If you are pregnant, breastfeeding, there is a chance you are pregnant or you are planning to become pregnant, consult the doctor, who will decide if you can take Risperdal.
- The following symptoms may occur in babies born to women who used Risperdal in the last trimester of pregnancy (the last three months of pregnancy): shaking, muscle stiffness and/or weakness, sleepiness, nervousness, breathing problems, or difficulty in feeding. If your baby develops any of these symptoms, you may need to inform the doctor.
- Risperdal can raise the levels of a hormone called prolactin, which may impact fertility (see Side effects).

■ Driving and use of machinery

Use of this medicine may cause tiredness, dizziness and vision problems. Therefore, do not drive a vehicle, operate machinery or tools without consulting the doctor first.

■ Important information regarding some of the ingredients of the medicine

Risperdal tablets contain a kind of sugar called lactose. If you suffer from intolerance to certain sugars, consult the doctor before taking Risperdal tablets. Risperdal 2 mg tablets contain the ingredient 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. Benzoic acid may cause an increase in jaundice (yellowing of the skin and eyes) in newborns (up to 4 weeks of age).

3. HOW SHOULD THE MEDICINE BE USED?

Always use according to the doctor's instructions.

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

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

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 or 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:

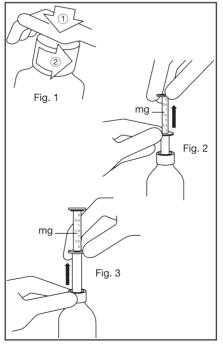
Mix the oral solution with any beverage that does not contain alcohol, except for tea.

The solution is provided with a measuring syringe. Use the measuring syringe to measure the exact amount.

Follow the instructions below:

Opening instructions: Figure 1: To open the cap, press down while turning counterclockwise. Child-resistant caps have significantly reduced the number of cases of medicine-induced poisoning each year. However, if you find it difficult to open the package, you can ask the pharmacist to remove the safety mechanism in the cap and

make it into a regular easy-to-open cap. Figure 2: Insert the measuring syringe into the bottle, hold the lower ring and pull the upper ring up until the mark that matches the number of milliliters or milligrams that you need to take. Figure 3: While holding the lower ring, remove the measuring syringe from the bottle and empty it, by pressing down on the upper ring, into any non-alcoholic beverage (except for tea). Close the bottle and wash the measuring syringe with water.



If you accidentally take a higher dosage

If you took an overdose, you may experience any of the following symptoms: sleepiness or tiredness, or you may have abnormal body movements, difficulty in standing up or walking, dizziness as a result of low blood pressure, abnormal heart rate or seizures. If you took an overdose, if you experience any of the listed symptoms or if a child 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 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 forgotten dose and take the next dose on time. If you forgot to take two or more doses, contact the doctor

Do not take a double dose to compensate for a forgotten

Adhere to the treatment regimen recommended by the doctor.

Even if there is an improvement in your health, do not stop the 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 has instructed you to stop treatment, gradually lower

the dosage 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

If you have further questions regarding use of the medicine, consult the doctor or pharmacist.

4. SIDE FEFFCTS

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 1-10 in 1,000 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, or slurred speech, even for a short period of time. These may be signs of a stroke.
- you experience tardive dyskinesia (uncontrollable ierking or twitching movements in the face, tongue or other parts of the body). Tell the doctor if you experience involuntary rhythmic movements of the tongue, mouth or face. The treatment with risperidone may have to be terminated.

Refer to a doctor immediately if you experience any of the following rare side effects - effects that occur in 1-10 in 10.000

- 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, and cause chest pain and difficulty breathing. If you experience any of these symptoms, seek medical attention immediately.
- you experience fever, muscle stiffness, sweating or a decrease in level of consciousness (a disorder called Neuroleptic malignant syndrome). Immediate medical treatment may be
- you are a man and experience a prolonged and painful erection. This is called priapism. Immediate medical treatment may be
- you experience a severe allergic reaction characterized by fever, swelling of the mouth, face, lip or tongue, shortness of breath, itching, skin rash or drop in blood pressure.

Additional side effects:

Very common side effects - effects that occur in more than 1 user in 10:

· 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 frozen movement, followed by restarting of the movement. Other signs of Parkinsonism can include: a slow shuffling walk, tremor while at rest, increased salivation and/or drooling, and loss of facial expression Sleepiness or reduced alertness.
- Headache.

Common side effects - effects that occur in 1-10 in 100

- Pneumonia, inflammation of the bronchi (bronchitis), common cold symptoms, sinus inflammation, urinary tract inflammation, 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 are uncommon and can include in men: breast swelling, inability to reach or maintain an erection, reduced libido or other sexual dysfunction. In women, the symptoms can include: breast discomfort, discharge of milk from the breasts, absence of menstrual periods or other menstrual cycle disturbances or fertility problems.
- Weight gain, increased appetite, decreased appetite.
- · Sleep disorders, nervousness, depression, anxiety, restlessness
- Dystonia: this is a condition involving slow or sustained involuntary contraction of the muscles. While this condition can involve any part of the body (and may be manifested by abnormal posture), it usually affects the facial muscles. This condition includes 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.
- Rapid heart rate, high blood pressure, shortness of breath. Sore throat, cough, nosebleed, stuffy nose. · Abdominal pain, abdominal discomfort, vomiting, nausea,

• Blurry vision, eye infection or conjunctivitis.

- constipation, diarrhea, indigestion, dry mouth, toothache.
- Rash, skin redness. • Muscle spasms, bone or muscle pain, back pain, joint pain.
- · Urinary incontinence (inability to hold it in). · Swelling of the body, hands or legs, fever, chest pain, weakness,
- fatigue, pain. Falling

Uncommon side effects - effects that occur in 1-10 in 1,000

- 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, low white blood cell count, 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.
- Alleraic reaction.
- Diabetes mellitus or worsening of diabetes mellitus, high blood sugar level, excessive drinking of water.
- Weight loss, malnutrition and low body weight due to loss of appetite.
- Increased level of cholesterol in the blood.
- Elated mood (mania), confusion, decreased sexual drive, nervousness, nightmares Unresponsiveness to stimulation, 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, attention
- disorders, 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 tearing,
- redness of the eyes. Spinning sensation (vertigo), ringing in the ears, ear pain. · Atrial fibrillation (irregular heart rhythm), 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 in respiratory passages, crackly lung sounds,

wheezing, voice disorder, respiratory system disorder

to hold in), very hard stools, difficulty swallowing, increased flatulence. · Hives (skin rash), itching, hair loss, thickening of the skin, eczema, dry skin, skin discoloration, acne, dandruff and itching

· Stomach or intestinal infection, stool incontinence (inability

- of the scalp or skin, skin problems, skin sores. An increase of CPK levels (creatine phosphokinase) in the blood, an enzyme which is sometimes released due to muscle breakdown.
- muscle weakness, neck pain. • Frequent passing of urine, inability to pass urine, pain when passing urine.

· Abnormal posture/body position, joint stiffness, joint swelling,

- · Inability to achieve erection, ejaculation disorders · Absence of menstrual periods, delayed menstrual periods or any other menstrual cycle disturbance.
- 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 gait.
- Feeling thirsty, general unwell feeling, chest discomfort, feeling down, 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 upon receiving treatment. Rare side effects - effects that occur in 1-10 in 10.000

- Abnormal secretion of a hormone that controls urine volume.
- Sleep walking.
- · Lack of emotion, inability to reach sexual satisfaction
- (orgasm).
- Not moving or responding while awake (catatonia).
- Coma due to uncontrolled diabetes mellitus.
- disturbances, eye rolling, eyelid margin crusting. Eye problems during cataract surgery. During cataract surgery,
- have taken Risperdal. · Dangerous decrease in the number of white blood cells in the
- Breathing difficulties (inability to breathe) while sleeping, rapid and shallow breathing.
- · Dandruff.
- (rhabdomyolysis)
- Increased levels of blood insulin (a hormone that regulates the sugar levels in the blood).
- Symptoms of drug withdrawal.

Yellowing of the skin and the eyes (jaundice).

- Life-threatening complications resulting from uncontrolled diabetes mellitus
- Serious allergic reaction with swelling that may involve the throat and lead to breathing difficulties. Lack of muscle movement in the digestive system that causes blockage

to risperidone, and therefore, may also occur when using risperidone: rapid heartbeat upon standing up. Additional side effects in children and adolescents

The following side effects were reported more often in children

diarrhea, and urinary incontinence. If a side effect occurs, if one of the side effects worsens, or

Reporting side effects Side effects can be reported to the Ministry of Health by clicking

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.

Store at a temperature below 30°C.

Hypromellose 2910 15 mPa.s, Magnesium stearate, Colloidal

Film-coating: Risperdal 1 mg:

glycol, Orange yellow S aluminum lake.

Risperdal Oral Solution:

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 2 mg tablets: The tablet is film-coated, rectangular,

on one side. Risperdal 4 mg tablets: The tablet is film-coated, rectangular, biconvex, green, with a score line, with the lettering ${
m RIS/~4}$

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

Shefayim 6099000, Israe Manufacturer and address:

Risperdal 1 mg tablets Risperdal 2 mg tablets Risperdal 3 mg tablets 1448028262-01

Risperdal 4 mg tablets 1448128263-01 Risperdal 1 mg/ml oral solution 1147429633-00

- Infection.

- Sleep-related eating disorders.
- Presence of sugar in the urine, low blood sugar level, high blood triglyceride levels (fat).

- Problems with blood vessels in the brain
- Shaking of the head. · Glaucoma (high intraocular pressure), eye movement
- 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 eye doctor if you are taking or
- blood of the type needed to protect against infections. Highly excessive water consumption that endangers the
- Abnormal heart rate
- Inflammation of the pancreas, intestinal blockage. • Swollen tongue, chapped lips, drug-related skin rash.
- · Breakdown of muscle fibers and muscle pain
- A delay in menstrual period, enlargement of the glands in the breasts, breast enlargement, discharge from the breasts.
- Very rare side effects effects that occur in less than 1 user

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

if you suffer from a side effect not mentioned in the leaflet, consult with the doctor.

contains:

anhydrous silica, Sodium lauryl sulfate.

Hypromellose 2910 5 mPa.s, Titanium dioxide, Talc, Propylene

glycol, Quinoline yellow, Indigotindisulfonate aluminum lake.

on the link "Report Side Effects of Drug Treatment" found on the Ministry of Health homepage (www.health.gov.il) that directs

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

Oral solution: Do not freeze. After opening, can be used for 3

6. FURTHER INFORMATION In addition to the active ingredient, the medicine also

Tablet core Lactose monohydrate, Maize starch, Microcrystalline cellulose,

Hypromellose 2910 5 mPa.s, Propylene glycol.

Risperdal 4 ma: Hypromellose 2910 5 mPa.s, Titanium dioxide, Talc, Propylene

Revised in June 2020.

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of that month.

Risperdal tablets

Hypromellose 2910 5 mPa.s, Titanium dioxide, Talc, Propylene glycol, Quinoline yellow.