

PATIENT PACKAGE INSERT IN ACCORDANCE WITH THE PHARMACISTS' REGULATIONS (PREPARATIONS) - 1986
The medicine is dispensed with a doctor's prescription only

Rispond 1, 2, 3, 4 Film-coated Tablets

Rispond Solution

Composition:
Rispond 1 tablets: each **Rispond 1** tablet contains:
Risperidone 1 mg
Rispond 2 tablets: each **Rispond 2** tablet contains:
Risperidone 2 mg

Rispond 3 tablets: each **Rispond 3** tablet contains:
Risperidone 3 mg
Rispond 4 tablets: each **Rispond 4** tablet contains:
Risperidone 4 mg
Rispond solution: each 1 ml contains:
Risperidone 1 mg

Inactive and allergenic ingredients 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 for the treatment of 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 disorders.
- 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 others.
- 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: antipsychotic 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 know of sensitivity (allergy) to risperidone or to any of the ingredients contained in the medicine. For the list of additional ingredients, see section 6 “Further information”.

Special warnings regarding use of this medicine:

- **Before treatment with Rispodn, tell the doctor if:**
 - you have a heart problem. For example,

irregular heart beat or you tend to have low blood pressure or you are taking medicines for your blood pressure. **Rispodn** 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 suffered from a condition whose symptoms include high fever, muscle stiffness, sweating or a decrease in level of consciousness (also called Neuroleptic Malignant Syndrome).
- you suffer from Parkinson's disease or dementia.
- you know that you have suffered from low white blood cell count in the past (which may, but not necessarily, have been caused by use of other medicines).
- you suffer from diabetes.
- you suffer from epilepsy.
- you are a man and you have suffered in the past from a prolonged or painful erection.
- you suffer from difficulty regulating body temperature or from overheating.
- you suffer from kidney problems.
- you suffer from liver problems.
- you suffer from a high level of the prolactin hormone in your blood or you have a prolactin-dependent tumor.
- you suffer from 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 **Rispodn**.

- In very rare cases, dangerously low numbers of white blood cells necessary for protection against infections have been observed in patients taking **Rispodn**. Your doctor may check your white blood cell count.
- **Rispodn** 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 risperidone, your doctor will check for signs indicating high sugar levels in the blood. In patients with pre-existing diabetes mellitus, sugar levels in the blood should be monitored regularly.
- **Rispodn** regularly 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 undergo an eye operation, tell your doctor that you are taking this medicine.

Elderly patients with dementia

In elderly patients with dementia there is a higher risk of stroke. Do not use **Rispodn** if you are suffering from dementia as a result of a stroke. During the course of treatment with **Rispodn**, you should be frequently checked by a doctor. Seek medical treatment immediately if you or your caregiver notice a sudden change in your mental state or sudden weakness or loss of sensation/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 commencing use for behavioral problems, other causes of aggressive behavior should be

ruled out.

If during treatment with **Rispodn** tiredness occurs, a change in the time of administration of the medicine may 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 the height of 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 if you are taking:

- Medicines that act on the brain e.g. sedatives (benzodiazepines), or some pain-killers (opiates), allergy medicines (some anti-histamines), as **Rispodn** may increase the sedative effect of all these.
- Medicines that may change the electrical activity of the heart, such as medicines for malaria, medicines to treat heart rhythm disorders, medicines for allergies (anti-histamines), some antidepressants or other medicines for mental problems.
- Medicines that cause a slow heart rate.
- Medicines that cause low potassium levels in the blood (such as some diuretics).
- Medicines to treat hypertension. **Rispodn** may lower blood pressure.
- Medicines to treat 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). **Rispodn** 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 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 problems).
- Antidepressants such as paroxetine, fluoxetine, tricyclic antidepressants.
- Beta blockers (to treat hypertension).
- Phenothiazines (such as medicines used to treat psychosis or sedatives).
- Cimetidine, ranitidine (medicines to lower stomach acidity).
- Itraconazole and ketoconazole (to treat fungal infections).
- Some 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 **Rispodn**.

Use of the medicine and food

Rispodn can be taken with or without food.

Rispodn use and alcohol consumption
Abstain from drinking alcohol during the course of treatment with **Rispodn**.

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 use **Rispodn**. The following symptoms may occur in babies born to women who used risperidone in the last trimester of pregnancy (the last three months of pregnancy): tremor, 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.

Rispodn can raise the levels of a hormone called prolactin, which may affect fertility (see side effects).

Driving and use of machinery

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

Important information regarding some of the ingredients of the medicine

Rispodn tablets contain a kind of sugar called lactose. If you suffer from intolerance to certain sugars, consult the doctor before taking **Rispodn** tablets.

Rispodn Oral Solution contains benzoic acid. The medicine contains 1.9 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 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 **Rispodn**, as per the doctor's instructions.

Patients suffering from liver or kidney problems: these patients should take a lower dose of **Rispodn**, according to the doctor's instructions. Use **Rispodn** with caution in these patients.

Do not exceed the recommended dose.

Directions for use:

Rispodn can be taken with or between meals.
Use of Rispodn Tablets: Swallow the tablets with water. **Rispodn 1** tablets: if necessary the tablets can be halved for immediate use. **Rispodn 2, Rispodn 3, Rispodn 4** tablets: do not halve the tablet. There is no information regarding crushing or chewing the tablet.

Use of Rispodn solution: The oral solution can be mixed with any beverage that does not contain alcohol, except for tea. Do not use the solution 3 months after first opening the bottle.

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

If you accidentally take too high a 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 and seizures.

If you took an overdose, if you experience any of the described 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 Rispodn

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 dose.

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 the doctor has explicitly instructed you to. Stopping treatment may cause a recurrence of the disease symptoms.

If the doctor has instructed you to stop treatment, gradually lower the dosage 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 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 **Rispodn** 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 time. These may be signs of a stroke; you experience tardive dyskinesia (uncontrollable jerking 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 **Rispodn** 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 users:

You experience blood clots in the veins, especially in the legs (the symptoms include swelling, pain, and redness in the leg), which may migrate via the blood vessels to the lungs, and cause chest pain and difficulty in 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 needed; you are a man and experience a prolonged and painful erection. This is called priapism. Immediate medical treatment may be necessary; 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 causes distorted movements) and sometimes even a sensation of movement stagnation, followed by a restarting of the movement. Additional signs of Parkinsonism can include: a slow shuffling walk, tremor 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 users:

Pneumonia, inflammation of the bronchi (bronchitis), common cold symptoms, sinus inflammation, urinary tract inflammation, ear infection, flu-like illness; **Rispodn** can cause elevated levels of the hormone prolactin which

can be detected in blood tests (that may, but not necessarily, cause the appearance of symptoms). Symptoms of high prolactin are uncommon and can include: breast swelling in men, inability to reach or maintain erection, reduced libido or other sexual dysfunctions. In women, the symptoms can include: breast discomfort, discharge of milk from the breasts, absence of menstrual period 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), usually the facial muscles are affected. 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; Tremor; Blurry vision, eye infection or conjunctivitis; Rapid heart rate, high blood pressure, shortness of breath; Sore throat, cough, nosebleed, nasal congestion; Abdominal pain or discomfort, vomiting, nausea, 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; Falls.

Uncommon side effects – effects that occur in 1-10 in 1,000 users:

Infection of the respiratory tract, 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 resulting from 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; Allergic 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 tingling of the skin; Oversensitivity of the eyes to light, dry eyes, increased tearing, redness of the eyes; Dizzy 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 the electrical activity of the heart (electrocardiogram or ECG), feeling of abnormal heartbeats (palpitations); Low blood pressure, low blood pressure upon standing up (consequently, some people taking **Rispodn** may feel weakness, dizziness 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 sounds from the lungs, wheezing, voice disorder, respiratory tract disorder; Infection of the intestine or stomach, stool incontinence (inability to hold it in), very hard stool, difficulty swallowing, increased flatulence; 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 sores; An increase in 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; inability to achieve erection, ejaculation disorders; Absence of menstrual period, 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 users:

Infection; Abnormal secretion of a hormone that controls urine volume; Sleep walking, sleep-related eating disorders; Presence of sugar in the urine, low sugar levels in the blood, high triglyceride levels in the blood (fats); 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 mellitus; Shaking of the head; Glaucoma (high intraocular pressure), eye movement disturbances, 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 **Rispodn**. If you need to undergo cataract surgery, tell your doctor if you are taking or have taken **Rispodn**; Dangerous decrease in the number of white blood cells of the type needed to protect against infections; Highly excessive water consumption that endangers the body; Abnormal heart rate; Breathing difficulties (inability to breathe) while sleeping, rapid and shallow breathing; Inflammation of the pancreas, intestinal blockage; 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) levels; Hardening of the skin; Decrease in body temperature, cold sensation in the hands and legs; Symptoms of drug withdrawal; Yellowing of the skin and the eyes (jaundice).

Very rare side effects – effects that occur in less than 1 user in 10,000:

Life-threatening complications resulting from uncontrolled diabetes mellitus; Serious 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 seen with the use of another medicine called paliperidone, a medicine that is very similar to risperidone, and therefore, may also occur when using risperidone: rapid heartbeat upon standing up.

Side effects of unknown frequency – the frequency can not be determined from the available data.

Severe or life-threatening rash, with blisters and peeling skin, that may begin in the mouth, nose, eyes and genitals and spread to other parts of the body (Stevens-Johnson syndrome or toxic epidermal necrolysis [TEN]).

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: feeling

sleepy or reduced alertness, fatigue (tiredness), headache, increased appetite, vomiting, 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 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>. Additionally, you can report to “[Unipharm Ltd.](#)”.

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 below 25°C and in a place protected from light. Solution: Do not use the solution if more than 3 months have passed since opening the bottle. Residue of the solution should be destroyed.

6. FURTHER INFORMATION

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

Tablets:

Lactose monohydrate; microcrystalline cellulose; pregelatinized starch; sodium staron glycolate; magnesium stearate; sodium lauryl sulfate; opadry.

Rispodn tablets 1 mg, 2 mg, 3 mg, and 4 mg contain 51 mg, 51 mg, 50 mg, and 50 mg lactose, respectively.

Solution:

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

What the medicine looks like and the contents of the pack:

Rispodn tablets are packaged in blister trays that are placed in a cardboard box. Each package of **Rispodn** contains 5, 7, 10, 14, 15, 20, 28 or 30 tablets. Not all package sizes may be marketed.

Rispodn 1 tablets are film-coated, round, biconvex, white with a score line on one side.

Rispodn 2 tablets are film-coated, round, biconvex, light-yellow in color.

Rispodn 3 tablets are film-coated, round, biconvex, light-green in color.

Rispodn 4 tablets are film-coated, round, biconvex, light-blue in color.

Rispodn Solution - the preparation is provided in a 30 ml glass bottle. The cardboard package contains the bottle of the preparation and a measuring syringe. The solution is clear and colorless.

Registration holder and address: Unipharm Ltd., P.O.Box 21429, Tel Aviv, 6121301.
Manufacturer and address: Unipharm Ltd., “Mevo Carmel” Industrial Park.

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

Rispodn 1 tablets: 134 58 31403 01

Rispodn 2 tablets: 134 59 31404 01

Rispodn 3 tablets: 134 60 31405 01

Rispodn 4 tablets: 134 86 31482 01

Rispodn Solution: 141 17 31711 01

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