

- Drop in blood pressure after standing. As a result of this, dizziness or faintness may occur in people using RESDON when they suddenly stand up or sit down, redness.
- Pneumonia caused by inhaling of food into the lungs, lung congestion, congestion of respiratory ways, crackly lung noise, impairment in voice, respiratory way disorder.
- Stomach or intestines infection, fecal incontinence, very hard faeces, difficulty in swallowing, flatulence.
- Hives, itching, hair loss, thickening of skin, eczema, dry skin, skin discoloration, acne, itching and scaling in the skin or in the scalp, skin disorder, skin lesion.
- Increased blood creatinine phosphokinase (CPK) in your blood. This enzyme is sometimes secreted as a result of breakdown of muscle fibers.
- Abnormal posture, joint stiffness, joint swelling, muscle weakness, neck pain.
- Pain when passing urine, frequent passing of urine or not being able to urinate.
- Erectile dysfunction in men, ejaculation disorder.
- Delay in menstrual periods, no menstruation or other menstrual problems.
- Enlargement of breast in men, breast discharge, sexual dysfunction, breast pain, breast discomfort, vaginal discharge.
- Swelling of face, mouth, eye or lips.
- Tremor (shaking), increase in body temperature.
- A change in the way you walk.
- Feeling thirsty, feeling unwell, chest discomfort, discomfort, joylessness.
- Increase in liver transaminase enzymes in your blood, increase in an enzyme called gamaglutamyl transferase, increase in liver enzymes.
- Pain during injection.

Rare

- Infection.
- Inappropriate secretion of the hormone that controls urine volume.
- Sugar in the urine, low blood sugar, high blood triglycerides.
- Lack of emotion, inability to reach orgasm.
- Neuroleptic Malignant Syndrome (confusion, loss of consciousness, low level of consciousness, high fever, severe muscle stiffness).
- Blood vessel problems in the brain.
- Coma due to uncontrolled diabetes.
- Shaking of the head.
- Increased pressure within the eyeball (glaucoma), 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) can happen if you are taking or have taken RESDON. If you need to have cataract surgery, be sure to tell your eye doctor if you are taking or have taken this medicine.
- Dangerously decrease in the type of white blood cells that help protecting your body against infections.
- Severe allergic reaction characterised by fever; swollen mouth, face, lip or tongue; shortness of breath, skin rash with itching and sometimes drop in blood pressure.
- Dangerously excessive intake of water.
- Irregular heart beat.
- Blood clots in the leg veins, blood clots in the lungs.
- Trouble breathing during sleep (sleep apnea); fast, shallow breathing.
- Inflammation of the pancreas, a blockage in the intestines.
- Swollen tongue, chapped lips, itching on skin related to drug.
- Dandruff.
- Breakdown of muscle fibers and pain in muscles (rhabdomyolysis).
- A delay in menstrual periods, enlargement of the glands in your breasts, breast enlargement, discharge from the breasts.
- Increased insulin (the hormone that controls blood sugar levels) in your blood.
- Prolonged erection (priapism) that may require medical treatment.
- Thickening of skin.
- Decreased body temperature, coldness in arms and legs.
- Symptoms of drug withdrawal.
- Yellowing of the skin and the eyes (jaundice).

Very rare

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

The following side effect has been seen with the use of another medicine called paliperidone that is very similar to risperidone, so this can also be expected with RESDON:

- 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. Feeling sleepy, or less alert, fatigue, headache, increased appetite, vomiting, common cold symptoms, nasal congestion, abdominal pain, dizziness, cough, fever, tremor, diarrhoea, and incontinence of urine.

These are the mild side effects of RESDON.

Reporting of side effects

Talk with your doctor, pharmacist or nurse if you experience any side effect that is included or not included in this patient information leaflet. Also, report the side effects you have encountered, to Turkish Pharmacovigilance Center (TUFAM) via information leaflet. Also, report the side effects you have encountered, to Turkish Pharmacovigilance Center (TUFAM) via clicking "Drug Side Effect Report" icon on www.ticik.gov.tr or via calling the side effect report line on 0800 314 00 08. By reporting experienced side effects, you will be contributing in obtaining more information regarding the safety of your drug. If you encounter any side effect that is not included in this patient information leaflet, inform your doctor or pharmacist.

5. How to store RESDON

Keep RESDON out of the reach and sight of children and store in its original package.

Store at room temperature below 25°C. Do not put in refrigerator and do not freeze. The product should be used within 3 months after opening the bottle. Do not keep the unused part.

Use in accordance with its expiry date.

Do not use RESDON after the expiry date on the package.

Do not use RESDON if you notice product and/or packaging defects.

Do not throw away drugs that have expired or are not being used! Give them to the collection system determined by the Ministry of Environment and Urbanism.

This patient information leaflet was approved on 10.04.2015.

PATIENT INFORMATION LEAFLET

RESDON 1 mg / ml oral solution For oral use.

- **Active ingredient:** Each 1 ml solution contains 1 mg risperidone.
- **Excipients:** Tartaric acid (E334), benzoic acid (E210), sorbitol 70% (E420), sodium hydroxide (E524), purified water.

Read this LEAFLET carefully before you start to use this medicine. It contains important information for you.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, please consult your doctor or pharmacist.
- This medicine has been prescribed for you personally. Do not give it to others.
- During the use of this medicine, when you visit a doctor or a hospital, tell your doctor that you are using this medicine.
- Follow the directives in this leaflet strictly. Do not use higher or lower dose of the medicine than the one recommended to you.

In this leaflet:

1. What RESDON is and what it is used for
2. What you need to know before you use RESDON
3. How to use RESDON
4. Possible side effects
5. How to store RESDON

Topics are included.

1. What RESDON is and what it is used for

- RESDON contains 1 mg risperidone as active substance in each 1 ml solution.
- RESDON is clear, colourless solution. RESDON is presented for use in bottles containing 100 ml oral solution.
- RESDON belongs to the group of drugs, named antipsychotics and used in case of a kind of a psychological disorder (psychosis).
- RESDON is used in the treatment of the following conditions:
 - It is used in treatment of conditions affecting your thoughts, feelings, and/or behaviours, such as hallucination (seeing, hearing, and feeling something not existing), delusion, mental confusion, aggression, paranoia, emotional and social shyness. RESDON also reduces the signs such as psychological breakdown, feeling of guilt, anxiety and stress felt by people in these conditions.
 - It is used for stabilizing the psychological state impaired (in instantly developing and long-term diseases; for controlling and/or explosive episodes observed in bipolar disorder (opposite changes in psychological state), in treatment of behaviours presenting mainly aggression or other destructive and other destructive behaviour disorders, in treatment of restlessness (aggressive signs, self-destruction, temper episodes, instant mood changes) due to autistic disorder in children and adolescents).

2. What you need to know before you use RESDON

Do not use RESDON:

- If you are allergic to risperidone or any of the other ingredients of RESDON.
- If you are suffering from a prolonged QT syndrome (a condition that can lead to severe arrhythmias in the heart and sudden deaths) or Torsades de Pointes (life-threatening irregular heart rhythm).

Use RESDON with caution in the following conditions:

- If you have a heart problem. This could be an irregular heart rhythm or if you are prone to low blood pressure or if you are using medicines for your blood pressure. RESDON may cause low blood pressure. Your dose may need to be adjusted.
- If you have any factors which could lead a stroke, such as high blood pressure, cardiovascular disorder or circulation problems in the brain.
- If you experienced involuntary rhythmic movements of the tongue, mouth and face.
- If you experienced a disorder called "neuroleptic malignant syndrome". The symptoms of this disease include fever, severe muscle stiffness, sweating or a lowered level of consciousness.
- If you have dementia related with Parkinson's disease or dementia.
- If 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).
- If you are diabetic or if you have the risk of developing diabetes.
- If you have cardiovascular disorder or blood vessel problems or blood vessel problems in the brain.
- If you have epilepsy or Parkinson's disease.
- If you are a man and you have ever had a prolonged or painful erection.
- If you have problems controlling your body temperature or overheating.
- If you had a heart attack or transient ischemic attack (temporary decrease in blood flow to the brain).
- If you have kidney or liver problems.
- If you have an abnormally high level of the hormone prolactin in your blood or if you have a tumour, which is possibly dependent on prolactin.
- If you have hereditary prolonged QT syndrome (heart beat rhythm disorder).
- If you or someone else in your family has a history of blood clots (as antipsychotics have been associated with formation of blood clots).

In patients receiving risperidone, very rarely, there have been reports of dangerous decreases in the number of white blood cells in some species required to fight infection. For this reason, your doctor may want to check your white blood cell count.

RESDON may cause you to gain weight. Gaining a certain amount of weight may affect your health negatively. Your doctor should monitor your weight regularly.

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

During eye surgery due to the blurred eye lens (cataract), the pupil (the black circle in the center of the eye) may not expand as needed. At the same time, the iris (colored part of the eye) may loosen during surgery, which can lead a damage in the eye. If you are planning to have an operation on your eye, be sure to tell your doctor that you are taking this medicine.

Elderly people with dementia

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

Medical treatment should be sought straight away if you or your care-giver notice a sudden change in your mental state or sudden weakness or numbness of your 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.

Also;

- Conventional and atypical antipsychotic drugs cause an increased risk of mortality when used in the treatment of elderly patients with dementia-related psychosis.

Please consult your doctor, even if these statements were applicable to you at any time in the past.

Taking RESDON with food and drink

RESDON may be taken before or after meal. You should avoid drinking alcohol when taking RESDON.

Pregnancy

Ask your doctor or pharmacist for advice before taking this medicine.

If you are pregnant, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine. The following symptoms may occur in newborn babies, if you used RESDON in the last trimester (last three months of your pregnancy): shaking with variable severity, muscle stiffness and/or weakness, sleepiness, agitation, breathing problems, and difficulty in feeding. If your baby develops any of these symptoms you should contact your doctor. RESDON can raise your levels of a hormone called prolactin that may affect male and female fertility (see section 4 Possible

side effects).

If you realize that you are pregnant during your treatment, consult your doctor or pharmacist immediately.

Breast-feeding

Ask your doctor or pharmacist for advice before taking this medicine.

Do not use RESDON during breastfeeding unless your doctor decides that it is absolutely necessary.

Driving and using machines

During treatment with RESDON, dizziness, tiredness, and vision problems may occur. Do not drive or use any tools or machines without talking to your doctor first.

Important information about some of the ingredients of RESDON

Sorbitol

If you have been told by your doctor previously that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.

Using RESDON with other medicines

Talk to your doctor if you are taking any of the following medicines:

- Medicines that work on your brain such as to help you calm down (benzodiazepines); some medicines for pain (opioids), medicines for allergy (some antihistamines), as risperidone may increase the sedative effect of all of these.
- Medicines that may change the electrical activity of your heart, such as medicines for malaria, heart rhythm problems, allergies (antihistamines), some antidepressants or other medicines for mental problems.
- Medicines that cause a slow heart beat.
- Medicines that cause low blood potassium (e.g. certain diuretics).
- Medicines for Parkinson's disease or epilepsy (like levodopa).
- Medicines to treat elevated blood pressure. RESDON may lower blood pressure.
- Diuretics used for heart problems or swelling of parts of your body due to a build up of too much fluid (e.g. furosemide or chlorothalidate). RESDON taken by itself or with furosemide, may have an increased risk of stroke or death in elderly people with dementia.

The following medicines may reduce the effect of risperidone:

- Rifampicin (a medicine for treating some infections).
- Carbamazepine, phenytoin (medicines for epilepsy).
- Phenytoin (a medicine for epilepsy and sleeping).

If you start or stop taking such medicines you may need a different dose of risperidone.

The following medicines may increase the effect of risperidone:

- Quinidine (used for certain types of heart disease).
- Antidepressants such as paroxetine, fluoxetine, tricyclic antidepressants.
- Medicines known as beta blockers (used to treat heart diseases and high blood pressure).
- Phenothiazines (e.g. used to treat psychological diseases or as tranquilizer).
- Cimetidine, ranitidine (medicines used to balance the acidity of stomach).

If you start or stop taking such medicines you may need a different dose of risperidone.

Tell your doctor or pharmacist if you are taking or have recently taken any prescribed or non-prescribed medicine.

3. How to use RESDON?

Instructions for proper use and dosage / application frequency:

Your doctor will tell you how long your treatment will last with RESDON and in what doses you should take the solution. Always take this medicine exactly as your doctor has told you. Do not stop or extend your treatment on your own. You should check with your doctor or pharmacist if you are not sure how to take RESDON. Depending on your disease, the daily dose of RESDON ranges from 0.50 milligram to 6 milligrams. Follow the instructions of your doctor.

The method of administration:

This medicine is used orally by mixing in a beverage except tea and alcohol. You can take RESDON before or after meal.

Figure 1. Take the pipette out of its protecting cover and sink it into the bottle from the top. Adjust the upper ring to the milliliter or milligram you need while holding the lower ring.

Figure 2. Hold the lower ring and remove the pipette from the bottle. Empty the pipette into a beverage except tea and alcohol. Close the bottle and wash the pipette with water. Put the pipette into its protecting cover until next use.

Different age groups:

Use in children:

- Schizophrenia:
- There is not enough experience with using it in children under 18 years old.
- Bipolar Mania:
- There is not enough experience with using it in children under 18 years old.
- Disruptive behaviour disorders:

For patients < 50 kg:

A starting dose of 0.25 mg once daily is recommended. If needed, this dosage can be individually adjusted by increments of 0.25 mg once daily not more frequently than every other day. The usual maintenance dose is 0.25 mg to 0.75 mg once a day.

For patients > 50 kg:

A starting dose of 0.50 mg once daily is recommended. If needed, this dosage can be individually adjusted by increments of 0.50 mg once daily not more frequently than every other day. The usual maintenance dose is 0.50 mg to 1.5 mg once a day.

There is not enough experience with using it in children under 5 years old.

• Autism:

Children and adolescents: For patients with body weight less than 20 kg, dosing should be 0.25 mg per day. For patients with body weight greater than or equal to 20 kg, dosing should be 0.50 mg per day.

Use in elderly:

Schizophrenia

A starting dose of 0.50 mg twice daily is recommended. This dosage can be gradually adjusted by your doctor to 1-2 mg twice daily.

Mania

The usual starting dose of 0.50 mg twice daily is recommended.

Depending on how you respond to treatment, your doctor may gradually increase your dose from 1 mg to 2 mg twice daily. Your doctor will tell you how many tablets and what dose you should take.

Special conditions:

Renal insufficiency:

Irrespective of the indication, starting and maintenance dosing of risperidone should be halved. The dose titration should be slower in these patients. Risperidone should be used with caution in these groups of patients.

Hepatic failure:

Irrespective of the indication, starting and maintenance dosing of risperidone should be halved. The dose titration should be

slower in these patients. Risperidone should be used with caution in these groups of patients.

If you notice that effect of RESDON is too strong or too weak, consult your doctor or pharmacist.

If you took more RESDON than you should:

If you took more RESDON than you were told to, talk to a doctor or a pharmacist immediately.

The following symptoms may be seen in patients who took more RESDON than they should: Sleepiness, tiredness, abnormal body movements, problems with standing and walking, feeling dizzy due to low blood pressure and abnormal heart beats or seizures.

If you forget to take RESDON:

If you forget to take your dose on time, take it as soon as you remember it. However, if it is almost time for your next dose, skip the missed dose and continue as usual. If you miss two or more doses, contact your doctor.

Do not take a double dose to make up for a forgotten dose.

Possible effects after stopping treatment with RESDON:

If you stop your treatment without consulting your doctor, the symptoms of your illness may reappear. Unless your doctor recommend otherwise, when you stop RESDON treatment, you should stop it by decreasing the dose. If you have more questions, consult your doctor or pharmacist.

4. Possible side effects

Like all medicines, there may be side effects in people sensitive to the ingredients of RESDON.

If you notice any side effects listed below, stop using RESDON and tell your doctor IMMEDIATELY or apply to the emergency department of the nearest hospital:

- If you experience swelling, pain and redness, especially in the legs. This could mean blood clots in the veins. This clot may travel through blood vessels to the lungs causing chest pain and difficulty in breathing. If you have dementia and if you notice a sudden change in your mental state or sudden weakness or numbness of your face, arms or legs, especially on one side, or slurred speech, even a short period of time. These may be signs of a stroke.
- If you have fever, muscle stiffness, sweating or a lowered level of consciousness. This could be the symptoms of a disorder called "neuroleptic malignant syndrome".
- If you are a man and you have ever had a prolonged or painful erection. This is called "priapism".
- If there are involuntary, rhythmic movements of the tongue, mouth and face. Withdrawal of risperidone may be needed.
- Allergic reactions which are characterized with fever, swelling of mouth, swelling of face, tongue and lips, difficult breathing, itching, skin redness and sometimes lower blood pressure may occur.

These all are very serious side effects. If you have any of these side effects, it means that you are severely allergic to RESDON. You may need immediate medical treatment or to be hospitalized.

All these very serious side effects may occur very rare.

Tell your doctor immediately if you experience:

Undesirable events are classified according to the following frequencies:

- Very common: may be seen at least 1 in 10 people.
- Common: may be seen less than 1 in 10 people but more than 1 in 100 people.
- Uncommon: may be seen less than 1 in 100 people but more than 1 in 1000 people.
- Rare: may be seen less than 1 in 1000 people but more than 1 in 10000 people.
- Very rare: may be seen less than 1 in 10000 people.
- Not known: cannot be estimated from the available data.

Very common

- Flu symptoms
- Difficulty in sleeping or resumption of sleeping
- Parkinsonism: The symptoms of this disease are: Slow or impaired body movements, muscle stiffness or tightness (makes you unable to move properly), sometimes even suddenly freezing and then restarting of body movement, slow walking and dragging feet, shaking during rest, increase in saliva secretion or watery mouth, no expression on the face.
- Drowsiness, decreased response
- Headache

Common

- Lung infection (pneumonia), chest infection (bronchitis), sinus infection (sinusitis), urinary tract infection, ear pain, flu-like
- RESDON can raise your levels of a hormone called prolactin in your blood. This condition may or may not show symptoms. If it does, following can be seen:
- Enlargement of the breasts in men, difficulty in reaching or maintaining erection or other sexual dysfunctions; breast discomfort in women, discharge from the breasts, delay in menstrual periods or other problems related to menstruation.
- Weight gain, increased or decreased appetite.
- Sleep disorder, nervousness, depression, condition of anxiety and fear, insomnia.
- Dystonia: This means slow or continuous involuntary muscle contraction. It can be seen in any part of the body and can cause an abnormal posture. It is mostly visible in facial muscles and results in abnormal movements of eyes, mouth, tongue and jaw.
- Dizziness
- Dyskinesia: It means the involuntary movements of muscles. These movements are repetitive and occur as contractions, twitches, or twitches.
- Shaking
- Blurred vision, conjunctivitis (pink eye).
- Fast beating heart, high blood pressure, difficulty in breathing.
- Sore throat, cough, nose bleeding, nose congestion.
- Abdominal pain or discomfort, vomiting, nausea, constipation, diarrhoea, indigestion, dry mouth, toothache.
- Rash, skin redness.
- Muscle spasms, bone or muscle pain, back pain, joint pain.
- Urinary incontinence.
- Swelling of the body, arms or legs, fever, chest pain, weakness, feeling exhausted, pain.
- Fall

Uncommon

- Infection of the respiratory ways, bladder infection, eye infection, tonsillitis, yeast infection of nails, infection under the skin, viral infection, inflammation caused by nits.
- Decrease in the count of white blood cells that help protecting your body against infections, decrease in platelets (blood cells that help you stop bleeding, low haemoglobin or red blood cell count (anaemia), decrease in count of red blood cells, increase in eosinophils (a type of white blood cells).
- Allergic reaction.
- Diabetes mellitus or worsening of pre-existing diabetes mellitus, increased blood sugar, polydipsia.
- Decreased appetite resulting in malnutrition and low body weight.
- Increase in blood cholesterol.
- Elated mood (mania), confusion, decreased sexual desire, nervousness, nightmares.
- Tardive dyskinesia: This means involuntary rhythmic movements of face, mouth and the tongue. You should tell your doctor immediately because withdrawal of RESDON may be needed.
- Reduced blood flow to the brain (stroke).
- Unresponsive to stimuli, loss of consciousness, lowered level of consciousness.
- Convulsions (seizures), fainting.
- A sudden urge to move parts of your body, balance disorder, abnormal coordination, feeling dizzy after standing up, disturbance in attention, speech disorder, taste disturbance or abnormal taste, reduced skin sensitivity to pain and touch, "pins and needles".
- Partial oversensitivity to light in eyes, dry eye, increase in tears, redness in the eye.
- Feeling of dizziness or spinning (vertigo), ringing in ears, ear pain.
- Atrial fibrillation (abnormal heart rhythm), interruption in conduction between the upper and lower parts of the heart, abnormal electrical conduction of the heart, prolonged QT interval in the heart, heart rate decreased, abnormal electric activity tracing of the heart (ECG), awareness of heart beating.