

## PACKAGE LEAFLET: INFORMATION FOR THE USER

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

1. What Risperidone is and what it is used for
2. What you need to know before you take Risperidone
3. How to take Risperidone
4. Possible side effects
5. How to store Risperidone
6. Contents of the pack and other information

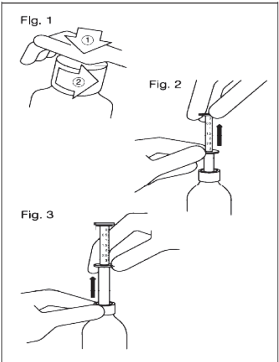
Risperidone can help alleviate the symptoms of your disease and stop your symptoms from coming back.

**Method of administration**  
For oral use.

Take the solution as follows:  
The solution comes with an oral syringe (pipette). Use only the syringe delivered with this medicine for measuring the dose prescribed by the physician. Measure the exact dose of medicine you need. Pay attention when measuring a small dose, for example for 0.25 mg, measure 0.25 ml (a quarter millilitre); for 0.5 mg, measure 0.5 ml (half a millilitre).

**Follow these steps:**

1. Remove the child-proof cap. Push the plastic screw cap down while turning it counter clockwise (Figure 1)
2. Insert the syringe into the bottle
3. While holding the bottom ring, pull the top ring up to the mark that corresponds to the number of millilitres or mg you need to take (Figure 2)
4. Holding the bottom ring, remove the entire syringe from the bottle (Figure 3)
5. Empty the syringe into any non-alcoholic drink, except for tea. Slide the upper ring down
6. Close the bottle
7. Rinse the syringe with some water and let it air dry.



**If you take more Risperidone than you should**

- See a doctor right away. Take the medicine pack with you.
- In case of overdose you may feel sleepy or tired, or have abnormal body movements, problems standing and walking, feel dizzy due to low blood pressure, or have abnormal heartbeats or fits.

**If you forget to take Risperidone**

If you forget to take a dose, 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 (two doses at the same time) to make up for a forgotten dose.

**If you stop taking Risperidone**

You should not stop taking this medicine unless told to do so by your doctor. Your symptoms may return. If your doctor decides to stop this medicine, your dose may be decreased gradually over a few days.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

**4 Possible side effects**

Like all medicines, this medicine can cause side effects, although not everybody gets them.

**Tell your doctor immediately if you experience any of the following uncommon side effects (may affect up to 1 in 100 people):**

- Have dementia and experience 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.
- Experience tardive dyskinesia (twitching or jerking movements that you cannot control in your face, tongue, or other parts of your body). Tell your doctor immediately if you experience involuntary rhythmic movements of the tongue, mouth and face. Withdrawal of Risperidone may be needed.

**Tell your doctor immediately if you experience any of the following rare side effects (may affect up to 1 in 1,000 people):**

- Experience blood clots in the veins, especially in the legs (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.
- Experience fever, muscle stiffness, sweating or a lowered level of consciousness (a disorder called “Neuroleptic Malignant Syndrome”). Immediate medical treatment may be needed.
- Are a man and experience prolonged or painful erection. This is called priapism. Immediate medical treatment may be needed.
- Experience severe allergic reaction characterised by fever, swollen mouth, face, lip or tongue, shortness of breath, itching, skin rash or drop in blood pressure.

The following other side effects may also happen:

**Very common (may affect more than 1 in 10 people)**

- Difficulty falling or staying asleep
- Parkinsonism: this condition may include: slow or impaired movement, sensation of stiffness or tightness of the muscles (making your movements jerky), and sometimes even a sensation of movement “freezing up” and then restarting. Other signs of parkinsonism include a slow shuffling walk, a tremor while at rest, increased saliva and/or drooling, and a loss of expression on the face.
- Feeling sleepy or less alert
- Headache.

**Common (may affect up to 1 in 10 people)**

- Pneumonia, infection of the chest (bronchitis), common cold symptoms, sinus infection, urinary tract infection, ear infection, feeling like you have the flu
- Raised levels of a hormone called “prolactin” found in a blood test (which may or may not 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 they 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 disorder, 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, and can include repetitive, spastic or writhing movements, or twitching.
- Tremor (shaking)
- Blurry vision, eye infection or “pink eye”
- Rapid heart rate, high blood pressure, shortness of breath
- Sore throat, cough, nosebleeds, stuffy nose
- Abdominal pain, abdominal discomfort, vomiting, nausea, constipation, diarrhoea, indigestion, dry mouth, toothache
- Rash, skin redness
- Muscle spasms, bone or muscle ache, back pain, joint pain
- Incontinence (lack of control) of urine
- Swelling of the body, arms or legs, fever, chest pain, weakness, fatigue (tiredness), pain
- Fall.

**Uncommon (may affect up to 1 in 100 people)**

- Infection of the breathing passages, bladder infection, eye infection, tonsillitis, fungal infection of the nails, infection of the skin, an infection confined to a single area of skin or part of the body, viral infection, skin inflammation caused by mites
- Decrease in the type of white blood cells that help to protect you against infection, white blood cell count decreased, decrease in platelets (blood cells that help you stop bleeding), Anaemia, decrease in red blood cells, increase in eosinophils (a type of white blood cell) in your blood
- Allergic reaction
- Diabetes or worsening of diabetes, high blood sugar, excessive drinking of water
- Weight loss, loss of appetite resulting in malnutrition and low body weight
- Increased cholesterol in your blood
- Elated mood (mania), confusion, decreased sexual drive, nervousness, nightmares
- Unresponsive to stimuli, loss of consciousness, low level of consciousness
- Convulsion (fits), fainting
- A restless urge to move parts of your body, balance disorder, abnormal coordination, dizziness upon standing, disturbance in attention, problems with speech, loss or abnormal sense of taste, reduced sensation of skin to pain and touch, a sensation of tingling, pricking, or numbness skin

- Oversensitivity of the eyes to light, dry eye, increased tears, redness of the eyes
- Sensation of spinning (vertigo), ringing in the ears, ear pain
- Atrial fibrillation (an abnormal 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 from your heart, slow heart rate, abnormal electrical tracing of the heart (electrocardiogram or ECG), a fluttering or pounding feeling in your chest (palpitations)
- Low blood pressure, low blood pressure upon standing (consequently, some people taking Risperidone may feel faint, dizzy, or may pass out when they stand up or sit up suddenly), 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, very hard stool, difficulty swallowing, excessive passing of gas or wind
- Hives (or “nettle rash”), itching, hair loss, thickening of skin, eczema, dry skin, skin discoloration, acne, flaky/ itchy scalp or skin, skin disorder, skin lesion
- An increase of CPK (creatine phosphokinase) in your blood, an enzyme which is sometimes released with muscle breakdown
- Abnormal posture, joint stiffness, joint swelling, muscle weakness, neck pain
- Frequent passing of urine, inability to pass urine, pain when passing urine
- Erectile dysfunction, ejaculation disorder
- 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, feeling unwell, chest discomfort, feeling “out of sorts”, discomfort
- Increased liver transaminases in your blood, increased GGT (a liver enzyme called gamma-glutamyltransferase) in your blood, increased liver enzymes in your blood
- Procedural pain.

**Rare (may affect up to 1 in 1,000 people)**

- Infection
- Inappropriate secretion of a hormone that controls urine volume
- Sleep walking
- Sleep-related eating disorder
- Sugar in the urine, low blood sugar, high blood triglycerides (a fat)
- Lack of emotion, inability to reach orgasm
- Not moving or responding while awake (catatonia)
- Blood vessel problems 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) can happen if you take or have taken Risperidone. If you need to have cataract surgery, be sure to tell your eye doctor if you take or have taken this medicine.
- Dangerously low numbers of a certain type of white blood cell needed to fight infection in your blood
- Dangerously excessive intake of water
- Irregular heart beat
- Trouble breathing during sleep (sleep apnoea), fast/ shallow breathing
- Inflammation of the pancreas, a blockage in the bowels
- Swollen tongue, chapped lips, rash 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 (a hormone that controls blood sugar levels) in your blood
- Hardening of the skin
- Decreased body temperature, a decrease in body temperature, coldness in arms and legs
- Symptoms of drug withdrawal
- Yellowing of the skin and the eyes (jaundice).

**Very rare (may affect up to 1 in 10,000 people)**

- 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.

The following side effect has been seen with the use of another medicine called paliperidone that is very similar to risperidone, so these can also be expected with Risperidone: rapid heartbeat upon standing.

**Additional side effects in children and adolescents**

In general, side effects in children are expected to be similar to those in adults. The following side effects were reported more often in children and adolescents (5 to 17 years) than in adults: feeling sleepy, or less alert, fatigue (tiredness), headache, increased appetite, vomiting, common cold symptoms, nasal congestion, abdominal pain, dizziness, cough, fever, tremor (shaking), diarrhoea, and incontinence (lack of control) of urine.

**Reporting of side effects**

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme at: [www.mhra.gov.uk/yellowcard](http://www.mhra.gov.uk/yellowcard) or search for MHRA Yellow Card in the Google Play or Apple App Store.

By reporting side effects you can help provide more information on the safety of this medicine.

**5 How to store Risperidone**

**Keep this medicine out of the sight and reach of children.**

Do not use this medicine after the expiry date which is stated on the bottle and outer packaging. The expiry date refers to the last day of that month.

This medicine does not require any special storage conditions.

Any unused oral solution should be discarded 3 months after opening the bottle.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

**6 Contents of the pack and other information**

**What Risperidone contains:**

- The active ingredient is risperidone
- Each ml oral solution contains 1 mg of risperidone
- The other ingredients are: benzoic acid (E 210), sorbitol 70% solution (E 420) and purified water.

**What Risperidone looks like and contents of the pack:**

- Risperidone Oral Solution is a clear colourless to yellow solution
- The product is available in 30 and 100 ml bottles with a 3 ml or 5 ml plastic oral syringe graduated at every 0.05 ml or a 5 ml plastic oral syringe graduated at every 0.1 ml.

Not all pack sizes may be marketed.

**Marketing Authorisation Holder and Manufacturer**

Marketing Authorisation Holder: Teva UK Limited, Ridings Point, Whistler Drive, Castleford, WF10 5HX, United Kingdom.  
Manufacturer: Teva Czech Industries s.r.o., Ostravska 305/29, Komarov, 747 70 Opava, Czech Republic.

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