

Package leaflet: Information for the user

Risperdal® Consta™ 50mg powder and solvent for prolonged-release suspension for intramuscular injection (risperidone)

Your medicine is available using the name above, but will be referred to as Risperdal Consta throughout this leaflet.

The vial and solvent syringe in this pack are labelled as 'Rispolept Consta'. 'Rispolept Consta' is the trademark of this product as marketed in Romania. This product is equivalent to the product marked in Ireland as 'Risperdal Consta'.

Read all of this leaflet carefully before you start using this medicine because it contains important information for you.

- 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.

What is in this leaflet:

- What Risperdal Consta is and what it is used for
- What you need to know before you use Risperdal Consta
- How to use Risperdal Consta
- Possible side effects
- How to store Risperdal Consta
- Contents of the pack and other information

1. What Risperdal Consta is and what it is used for

Risperdal Consta belongs to a group of medicines called 'antipsychotics'.

Risperdal Consta is used to maintain the treatment of schizophrenia, where you may see, hear or feel things that are not there, believe things that are not true or feel unusually suspicious, or confused.

Risperdal Consta is intended for patients who are currently treated with oral (e.g. tablets, capsules) antipsychotics.

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

2. What you need to know before you use Risperdal Consta

Do not use Risperdal Consta

- If you are allergic to risperidone or any of the other ingredients of this medicine (listed in section 6).

Warnings and precautions

- If you have never taken any form of Risperdal, you should begin with oral Risperdal before beginning treatment with Risperdal Consta.

Talk to your doctor or pharmacist before using Risperdal Consta if:

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

As dangerously low numbers of a certain type of white blood cell needed to fight infection in your blood has been seen very rarely with patients using Risperdal Consta, your doctor may check your white blood cell counts. Even if you have previously tolerated oral risperidone, rarely allergic reactions occur after receiving injections of Risperdal Consta. Seek medical attention right away if you experience a rash, swelling of your throat, itching, or problems breathing as these may be signs of a serious allergic reaction.

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

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

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

During an operation on the eye for cloudiness of the lens (cataract), the pupil (the black circle in the middle of your eye) may not increase in size as needed. Also, the iris (the coloured part of the eye) may become floppy during surgery and that may lead to eye damage. If you are planning to have an operation on your eye, make sure you tell your eye doctor that you are using this medicine.

Elderly people with dementia

Risperdal Consta is not for use in elderly people with dementia.

Medical treatment should be sought straight away if you or your carer 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.

People with kidney or liver problems

Although oral risperidone has been studied, Risperdal Consta has not been studied in patients with kidney or liver problems. Risperdal Consta should be administered with caution in this patient group.

Other medicines and Risperdal Consta

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

It is especially important to talk to your doctor or pharmacist if you are taking any of the following:

- Medicines that work on your brain to help you calm down (benzodiazepines), or some medicines for pain (opiates), 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 (anti-histamines), some antidepressants or other medicines for mental problems
- Medicines that cause a slow heart beat
- Medicines that cause low blood potassium (such as certain diuretics)
- Medicines for Parkinson's disease (such as levodopa)
- Medicines to treat raised blood pressure. Risperdal Consta can lower blood pressure
- Water tablets (diuretics) used for heart problems or swelling of parts of your body due to a build-up of too much fluid (such as furosemide or chlorothiazide). Risperdal Consta 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)
- Phenobarbital

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 high blood pressure)
- Phenothiazines (such as medicines used to treat psychosis or to calm down)
- Cimetidine, ranitidine (blockers of the acidity of stomach)
- Itraconazole and ketoconazole (medicines for treating fungal infections)
- Certain medicines used in the treatment of HIV/AIDS, such as ritonavir
- Verapamil, a medicine used to treat high blood pressure and/or abnormal heart rhythm
- Sertraline and fluvoxamine, medicines used to treat depression and other psychiatric disorders.

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

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

Risperdal Consta with food, drink and alcohol

You should avoid drinking alcohol when using Risperdal Consta.

Pregnancy, breast-feeding and fertility

- If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before using this medicine. Your doctor will decide if you can use it
- The following symptoms may occur in newborn babies, of mothers that have used Risperdal Consta in the last trimester (last three months of their pregnancy): shaking, muscle stiffness, and/or weakness, sleepiness, agitation, breathing problems, and difficulty in feeding. If your baby develops any of these symptoms you may need to contact your doctor
- Risperdal Consta can raise your levels of a hormone called "prolactin" that may impact fertility (see 'Possible side effects').

Driving and using machines

Dizziness, tiredness, and vision problems may occur during treatment with Risperdal Consta. Do not drive or use any tools or machines without talking to your doctor first.

Risperdal Consta contains less than 1mmol sodium (23mg) per dose, i.e., essentially 'sodium-free'.

3. How to use Risperdal Consta

Always use this medicine exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure.

Risperdal Consta is given as an intramuscular injection either in the arm or buttock every two weeks, administered by a health care professional. Injections should be alternated between the right and left sides, and should not be given intravenously.

The recommended dose is as follows:

Adults

Starting dose

If your daily dose of oral (e.g. tablets) risperidone was 4mg or less for the last two weeks, your starting dose should be 25mg Risperdal Consta.

If your daily dose of oral (e.g. tablets) risperidone was more than 4mg for the last two weeks, you may be given 37.5mg Risperdal Consta as a starting dose.

If you are currently treated with other oral antipsychotics than risperidone, your starting dose of Risperdal Consta will depend on your current treatment. Your doctor will choose Risperdal Consta 25mg or 37.5mg.

Your doctor will decide on the dose of Risperdal Consta that is right for you.

Maintenance dose

- The usual dose is 25mg every two weeks as an injection
- A higher dose of 37.5 or 50mg may be necessary. Your doctor will decide on the dose of Risperdal Consta that is right for you
- Your doctor may prescribe oral Risperdal for the first three weeks following your first injection.

If you are given more Risperdal Consta than you should

- People who have been given more Risperdal Consta than they should have experienced the following symptoms: sleepiness, tiredness, abnormal body movements, problems with standing and walking, dizziness from low blood pressure, and abnormal heart beats. Cases of abnormal electrical conduction in the heart and convulsion have been reported
- See a doctor right away.

If you stop using Risperdal Consta

You will lose the effects of the medicine. You should not stop this medicine unless told to do so by your doctor as your symptoms may return. Be sure not to miss your appointments when you are supposed to receive your injections every two weeks. If you cannot keep your appointment, be sure to contact your doctor right away to discuss another date when you can come in for your injection. If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

Use in children and adolescents

Risperdal Consta is not for people who are under 18 years old.

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 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
- 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 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 involuntary rhythmic movements of the tongue, mouth and face. Withdrawal of risperidone 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. Even if you have previously tolerated oral risperidone, rarely allergic reactions occur after receiving injections of Risperdal Consta.

The following side effects may happen:

Very common side effects (may affect more than 1 in 10 people):

- Common cold symptoms
- Difficulty falling or staying asleep
- Depression, anxiety
- 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
- Headache.

Common side effects (may affect up to 1 in 10 people):

- Pneumonia, infection of the chest (bronchitis), sinus infection
- Urinary tract infection, feeling like you have the flu, anaemia
- 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
- High blood sugar, weight gain, increased appetite, weight loss, decreased appetite
- Sleep disorder, irritability, decreased sexual drive, restlessness, feeling sleepy, or less alert
- 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
- Rapid heart rate
- Low blood pressure, chest pain, high blood pressure
- Shortness of breath, sore throat, cough, stuffy nose
- Abdominal pain, abdominal discomfort, vomiting, nausea, stomach or intestinal infection, constipation, diarrhoea, indigestion, dry mouth, toothache
- Rash
- Muscle spasms, bone or muscle ache, back pain, joint pain
- Incontinence (lack of control) of urine
- Erectile dysfunction
- Loss of menstrual periods
- Leakage of milk from the breasts
- Swelling of the body, arms or legs, fever, weakness, fatigue (tiredness)
- Pain
- A reaction at the injection site, including itching, pain or swelling
- Increased liver transaminases in your blood, increased GGT (a liver enzyme called gamma-glutamyltransferase) in your blood
- Fall.

Uncommon side effects (may affect up to 1 in 100 people):

- Infection of the breathing passages, bladder infection, ear 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, abscess under the skin
- White blood cell count decreased, decrease in platelets (blood cells that help you stop bleeding), decrease in red blood cells
- Allergic reaction
- Sugar in the urine, diabetes or worsening of diabetes
- Loss of appetite resulting in malnutrition and low body weight
- High blood triglycerides (a fat), increased cholesterol in your blood
- Elated mood (mania), confusion, inability to reach orgasm, nervousness, nightmares
- 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 Risperdal Consta may be needed
- Sudden loss of blood supply to brain (stroke or "mini" stroke)
- Loss 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 of skin
- Eye infection or "pink eye", 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 upon standing (consequently, some people using Risperdal Consta may feel faint, dizzy, or may pass out when they stand up or sit up suddenly)
- Fast, shallow breathing, congestion of breathing passages, wheezing, nosebleeds
- Stool incontinence, difficulty swallowing, excessive passing of gas or wind
- Itching, hair loss, eczema, dry skin, skin redness, skin discoloration, acne, flaky, itchy scalp or skin
- An increase of CPK (creatine phosphokinase) in your blood, an enzyme which is sometimes released with muscle breakdown
- Joint stiffness, joint swelling, muscle weakness, neck pain
- Frequent passing of urine, inability to pass urine, pain when passing urine
- Ejaculation disorder, a delay in menstrual periods, missed menstrual periods or other problems with your cycle (females), development of breasts in men, 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"
- Hardening of the skin
- Increased liver enzymes in your blood
- Procedural pain.

Rare side effects (may affect up to 1 in 1,000 people):

- Decrease in the type of white blood cells that help to protect you against infection
- Inappropriate secretion of a hormone that controls urine volume
- Low blood sugar
- Excessive drinking of water
- Lack of emotion
- Neuroleptic malignant syndrome (confusion, reduced or loss of consciousness, high fever, and severe muscle stiffness)
- Low level of consciousness
- Shaking of the head
- Problems with movement of your eyes, eye rolling, oversensitivity of the eyes to light
- Eye problems during cataract surgery. During cataract surgery, a condition called intraoperative floppy iris syndrome (IFIS) can happen if you use or have used Risperdal Consta. If you need to have cataract surgery, be sure to tell your eye doctor if you use or have used this medicine
- Irregular heart beat
- Dangerously low numbers of a certain type of white blood cell needed to fight infection in your blood, increase in eosinophils (a type of white blood cell) in your blood, blood clot in the legs, blood clot in the lungs
- Trouble breathing during sleep (sleep apnea)
- Pneumonia caused by inhaling food, lung congestion, crackly lung sounds, voice disorder, breathing passage disorder
- Inflammation of the pancreas, a blockage in the bowels
- Very hard stool
- Rash on skin related to drug
- Hives (or "nettle rash"), thickening of skin, dandruff, skin disorder, skin lesion
- Breakdown of muscle fibers and pain in muscles (rhabdomyolysis)
- Abnormal posture
- Breast enlargement, discharge from the breasts
- Decreased body temperature, discomfort
- Yellowing of the skin and the eyes (jaundice)
- Severe allergic reaction characterised by fever, swollen mouth, face, lip or tongue, shortness of breath, itching, skin rash and sometimes drop in blood pressure
- Dangerously excessive intake of water
- Increased insulin (a hormone that controls blood sugar levels) in your blood
- Blood vessel problems in the brain
- Unresponsive to stimuli
- Coma due to uncontrolled diabetes
- Sudden loss of vision or blindness
- Glaucoma (increased pressure within the eyeball), eyelid margin crusting
- Flushing, swollen tongue
- Chapped lips
- Priapism (a prolonged penile erection that may require surgical treatment)
- Enlargement of the glands in your breasts
- A decrease in body temperature, coldness in arms and legs
- Symptoms of drug withdrawal.

Very rare side effects (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 Risperdal Consta: Rapid heartbeat upon standing.

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 HPRa Pharmacovigilance, Earlsfort Terrace, IRL – Dublin 2
Tel: +353 1 6764971 Fax: +353 1 6762517
Website: www.hpra.ie E-mail: medsafety@hpra.ie

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

5. How to store Risperdal Consta**Keep this medicine out of the sight and reach of children.**

Do not use this medicine after the expiry date (Exp) which is marked on the carton. This refers to the last day of that month.

Store the entire dose pack in the refrigerator (2-8°C). If refrigeration is unavailable, the pack can be stored at room temperature (below 25°C) for a maximum of 7 days before use.

Use within 6 hours of reconstitution (if stored below 25°C). Store in the original package.

If your doctor tells you to stop using the medicine, please take them back to the pharmacist for safe disposal. Only keep the medicine if your doctor tells you to.

Do not use this medicine if you notice discoloration, damage or any other signs of deterioration.

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

6. Contents of the pack and other information**What Risperdal Consta contains**

The active substance is risperidone. Each Risperdal Consta powder and solvent for prolonged-release suspension for injection contains 50mg risperidone.

The other ingredients are:
Powder for suspension for injection poly (d,l-lactide-co-glycolide).

Solvent (solution):
Polysorbate 20, Carmellose sodium, Disodium hydrogen phosphate dihydrate, Citric acid anhydrous, Sodium chloride, Sodium hydroxide, Water for injection.

What Risperdal Consta looks like and contents of the pack

One vial containing the powder for prolonged-release suspension for injection.

One syringe filled with 2ml of clear, colourless liquid to be added to the powder for prolonged-release suspension for injection.

One West-Medimop Vial Adapter® for reconstitution (referred as Vial Adapter).

Two Terumo SurGuard® 3 needles for intramuscular injection (a 21G UTW 1-inch (0.8 mm x 25 mm) safety needle with needle protection device for deltoid administration and a 20G TW 2-inch (0.9 mm x 51 mm) safety needle with needle protection device for gluteal administration).

Manufacturer

Manufactured by:
Janssen Pharmaceutica NV, Turnhoutseweg 30, B-2340, Beerse, Belgium.

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This medicinal product is authorised in the Member States of the EEA under the following names:

Austria: RISPERDAL CONSTA
Belgium: RISPERDAL CONSTA
Bulgaria: РИСПОЛЕПТ КОНСТА
Cyprus: RISPERDAL CONSTA
Czech Republic: RISPERDAL CONSTA
Denmark: RISPERDAL CONSTA
Estonia: RISPOLEPT CONSTA
Finland: RISPERDAL CONSTA
France: RISPERDAL CONSTA LP
Germany: RISPERDAL CONSTA 25mg, 37,5mg, 50mg
Greece: RISPERDAL CONSTA
Hungary: RISPERDAL CONSTA
Iceland: RISPERDAL CONSTA
Ireland: RISPERDAL CONSTA
Italy: RISPERDAL
Lithuania: RISPOLEPT CONSTA
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