Warnings and precautions

You should avoid drinking alcohol when using Risperdal Consta.

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

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

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.

The name of your medicine is Risperdal Consta 25mg, 37.5mg, 50mg but it will be referred as Risperdal Consta throughout this leaflet.

What is in this leaflet

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

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

2. Possible side effects

If you get any side effects, tell your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

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

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 buttck every two weeks, administered by a healthcare 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 anti-psychotics 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. 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 or pharmacist immediately if:

- 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 breathlessness. If you notice any of these symptoms seek medical advice immediately
- Have diarrhea 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
- Experience involuntary rhythmic movements of the tongue, face or limbs, which may be associated with prolonged or painful erection. This is called priapism. Immediate medical treatment may be needed
- Experience loss of muscle strength or movement, joint stiffness and pain. If you notice any of these symptoms seek medical advice immediately
- Have a condition whose symptoms include high temperature, muscle stiffness, abnormal body movements or breathing difficulties (see Possible side effects).
- People with diabetes mellitus blood glucose should be monitored regularly.
- 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 relax and calm down (such as medicines used to treat psychosis or to calm down)
- Antidepressants such as paroxetine, fluoxetine, tricyclic antidepressants
- Antihistamines
- Other medicines that may increase the sedative effect of all of these medicines.
- Other 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 pressure (such as certain diuretics)
- Medicines for Parkinson's disease (such as levodopa)
- Medicines to treat raised blood pressure. Risperdal Consta can lower blood pressure
- Oral tablets (potassium) used for heart problems or swelling of parts of your body due to a buildup of too much fluid (such as furosemide or hydrochlorothiazide). Risperdal Consta taken by mouth or with furosemide, may have increased risk of stroke or death in elderly people with dementia.
- Medicines for blood clots (such as certain diuretics)
- Medicines for the treatment of HIV/AIDS, such as ritonavir, lopinavir, atazanavir, saquinavir or nelfinavir
- Medicines that may be used with Risperdal Consta

You should avoid drinking alcohol when using Risperdal Consta.

If you have any side effects, tell your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

The name of your medicine is Risperdal Consta 25mg, 37.5mg, 50mg but it will be referred as Risperdal Consta throughout this leaflet.

What is in this leaflet

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

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

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. Your dose may need to be adjusted
- You are elderly
- You do not think you have that medicine can cause low blood pressure. Your dose may need to be adjusted
- You have any factors which would favour having a stroke, such as high blood pressure, cardiovascular disorder or circulation disorders of the brain
- You have ever had 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 Neurontic 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 a diabetic
- You have epilepsy
- You are a man and have ever had a prolonged or painful erection
- You have difficulty controlling your 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 increased risk of blood clots.

Risperdal Consta with food, drink and alcohol

You should avoid drinking alcohol when using Risperdal Consta.

Pregnancy, breastfeeding 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').

Drinking and using medicines

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.
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 risperdone, rare 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 (myoclonus), 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, anemia
- 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 postures), dystonia often involves muscles of the face, including abnormal movements of the eyes, mouth, tongue or jaw

**Dizziness**

Dizziness is a condition involving involuntary muscle movements, and can include repetitive, spastic or wobbling movements, or trembling.

**Tremor (shaking)**

**Blurred vision**

**Rapid heart rate**

**Low blood pressure, chest pain, high blood pressure**

**Shortness of breath, cough, stuffy nose**

**Abdominal pain, abdominal discomfort, vomiting, nausea, stomach or intestinal infection, constipation, diarrhea, 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**

**Common cold symptoms**

**Increase in body temperature, chest**

**Chills, headache.**

**Erythema**

**Fever**

**Sweat**

**Increased saliva or drop in blood pressure**

**Uncontrollable movements in the mouth and face**

**Tremor while at rest, increased saliva and/or drooling**

**Movement**

**Loss of consciousness**

**High blood triglycerides (a fat),**

**Loss of appetite resulting in malnutrition and low body weight**

**Sugar in the urine,**

**Abscess under the skin**

**Increased risk of skin cancer**

**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 (female), 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 apnoea)**

**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 'hurt rash'), thickening of skin, dandruff, skin disorder, skin lesion**

**Breakdown of muscle fibers and pain in muscles (rhabdomyolysis)**

**Abnormal posture**

**Breast engorgement, 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 stimulus**

**Coma due to uncontrollable diabetes**

**Sudden loss of vision or blindness**

**Glaucoma (increased pressure within the eyeball),**

**Shaking, swollen tongue**

**Chapped lips**

**Prisial (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 heart beat upon standing.

**Reporting of side effects**

If you get any side effects, talk to your doctor, pharmacist or nurse. 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/yellcard.

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

**5 How to store Risperdal Consta**

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. Store in the original package in order to protect from light. Keep out of the sight and reach of children. Do not use Risperdal Consta after the expiry date which is stated on the carton after ‘Expiry’. The expiry date refers to the last day of that month.

**Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to 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 intramuscular injection contains either 25mg, 37.5mg or 50mg of risperidone.

The other ingredients are: Polygeline 7525 DL, D1-lactic acid-glycolide

**Solvent (sodium hydroxide solution)**

The solvent contains polysorbate 20, camellia soadum, disodium hydrogen phosphate diphosphate, citric acid anhydrous, sodium chloride, sodium hydroxide and water for injection.

The pack contains everything required to reconstitute and administer the product:

- A vial with white powder containing the active part of the medicine risperidone.
- A pre-filled syringe containing Solvent for Risperdal Consta (a liquid to make up the powder).
- Two needles for intramuscular injection (a 21G UTW 1-inch [0.8mm x 25mm] safety needle with Needle-Pro safety device for deltoid administration and a 20G TW 2 [1.0mm x 50mm] safety needle with Needle-Pro safety device for gluteal administration).
- One AliStar® Smart mine Needle Free Vial Access Device for reconstitution.

Manufactured by: Janssen Pharmaceutica N.V., Turnhoutseweg 30, 2340 Beerse, Belgium. Procured from within the EU and repackaged by the Product Licence holder: B&G Healthcare, Unit 4, Bridford Road, Ruislip, Middlesex, HA4 0NL, UK.

Risperdal® Consta® 25mg: PL 18799/2511

Risperdal® Consta® 37.5mg: PL 18799/2512

Risperdal® Consta® 50mg: PL 18799/2513

Leafllet date: 14.06.2016

Risperdal Consta is a registered trademark of Johnson & Johnson.
IMPORTANT INFORMATION FOR HEALTHCARE PROFESSIONALS

Important information
Risperdal® Consta® requires close attention to these step-by-step Instructions for Use to help ensure successful administration.

Use components provided
The components in this dose pack are specifically designed for use with Risperdal® Consta®. Risperdal® Consta® must be reconstituted only in the diluent supplied in the dose pack.

Do not substitute ANY components of the dose pack.
Do not store suspension after reconstitution.

Proper dosing

The entire contents of the vial must be administered to ensure intended dose of Risperdal® Consta® is delivered.

SINGLE-USE DEVICE

Do not reuse. Medical devices require specific material characteristics to perform as intended. These characteristics have been verified for single use only. Any attempt to re-process the device for subsequent re-use may adversely affect the integrity of the device or lead to deterioration in performance.

Dose pack contents

Danafil® Filled Syringe
WestMedrap® Vial Adapter®
Spike
Diluent
White cap
Coloured cap
Vial
Microspheres

Step 1 Assemble components

Take out dose pack

Wall 30 minutes
Remove dose pack from the refrigerator and allow to sit at room temperature for at least 30 minutes before reconstituting.
Do not warm any other way.

Connect vial adapter to vial

Remove cap from vial
Flip off coloured cap from vial.
Wipe top of the grey stopper with an alcohol swab. Allow to air dry.
Do not remove grey rubber stopper.

Prepare vial adapter
Hold sterile blister as shown. Peel back and remove paper backing.
Do not remove vial adapter from blister.
Do not touch spike tip at any time. This will result in contamination.

Connect vial adapter to vial
Place vial on a hard surface and hold by the base. Center vial adapter over the grey rubber stopper. Push vial adapter straight down onto vial top until it snaps securely into place.
Do not place vial adapter on an angle or diluent may leak upon transfer to the vial.

Connect pre-filled syringe to vial adapter

Remove sterile blister
Remove vial adapter from sterile blister only when you are ready to remove the white cap from the pre-filled syringe.
Keep vial vertical to prevent leakage. Hold base of vial and pull up on the sterile blister to remove.
Do not shake.
Do not touch exposed luer opening on vial adapter. This will result in contamination.
Use proper grip
Hold by white collar at the tip of the syringe.
Do not hold syringe by the glass barrel during assembly.

Remove cap
Holding the white collar, snap off the white cap.
Do not twist or cut off the white cap.
Do not touch syringe tip. This will result in contamination.

The broken-off cap can be discarded.

Step 2 Reconstitute microspheres

Inject diluent
Inject entire amount of diluent from syringe into the vial.
Vial contents will now be under pressure. Keep holding the plunger rod down with thumb.

Suspend microspheres in diluent
Continuing to hold down the plunger rod, shake vigorously for at least 10 seconds, as shown.
Check the suspension. When properly mixed, the suspension appears uniform, thick and milky in colour. Microspheres will be visible in the liquid. Immediately proceed to the next step so suspension does not settle.

Transfer suspension to syringe
Invert vial completely. Slowly pull plunger rod down to withdraw entire contents from the vial into the syringe.

Remove vial adapter
Hold white collar on the syringe and unscrew from vial adapter. Tear section of the vial label at the perforation. Apply detached label to the syringe for identification purposes.
Discard both vial and vial adapter appropriately.
**Step 3** Attach Needle

**Select appropriate needle**
Choose needle based on injection location (gluteal or deltoid).

**Attach needle**
Peel blister pouch open part way and use to grasp the base of the needle, as shown.

*Holding the white collar on the syringe, attach syringe to needle luer connection with a firm clockwise twisting motion until snug.*

*Do not touch needle luer opening. This will result in contamination.*

**Resuspend microspheres**
Fully remove the blister pouch. Just before injection, shake syringe vigorously again, as some settling will have occurred.

**Secure needle in safety device**
Using one hand, place needle safety device at a 45 degree angle on a hard, flat surface. Press down with a firm, quick motion until needle is fully engaged in safety device.

**Avoid needle stick injury:**
*Do not use two hands.*
*Do not intentionally disengage or mishandle the needle safety device.*
*Do not attempt to straighten the needle or engage the safety device if the needle is bent or damaged.*

**Properly dispose of needles**
Check to confirm needle safety device is fully engaged. Discard in an approved sharps container. Also discard the unused needle provided in the dose pack.

**Step 4** Inject dose

**Remove transparent needle protector**
Move the needle safety device back towards the syringe, as shown. Then hold white collar on syringe and carefully pull the transparent needle protector straight off.

*Do not twist transparent needle protector, as the luer connection may loosen.*

**Remove air bubbles**
Hold syringe upright and tap gently to make any air bubbles rise to the top. Slowly and carefully press plunger rod upward to remove air.

**Inject**
Immediately inject entire contents of syringe intramuscularly (IM) into the gluteal or deltoid muscle of the patient. Gluteal injection should be made into the upper outer quadrant of the gluteal area.

*Do not administer intravenously.*