PATIENT INFORMATION LEAFLET

SCHEDULING STATUS

Schedule 5

PROPRIETARY NAME, STRENGTH AND PHARMACEUTICAL FORM

RISPERDAL® CONSTA 25 mg (Long-Acting Suspension for Intramuscular Injection)

RISPERDAL® CONSTA 37,5 mg (Long-Acting Suspension for Intramuscular Injection)

RISPERDAL® CONSTA 50 mg (Long-Acting Suspension for Intramuscular Injection)

RISPERIDONE

Read all of this leaflet carefully before you are given RISPERDAL CONSTA

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor or your pharmacist.
- **RISPERDAL CONSTA** has been prescribed for you personally and you should not share your medicine with other people. It may harm them, even if their symptoms are the same as yours.

1. WHAT RISPERDAL CONSTA CONTAINS

RISPERDAL CONSTA is an antipsychotic medicine. The actual medicine in RISPERDAL CONSTA is risperidone. RISPERDAL CONSTA is an extended release formulation, consisting of a long-acting powder containing risperidone, dissolved in a liquid solution for injection.

Inactive ingredients: The diluent contains: Carmellose sodium 40mPA.s, citric acid anhydrous disodium, hydrogen phosphate dehydrate, polysorbate 20, sodium chloride, sodium hydroxide, water for injection.

RISPERDAL CONSTA is available in doses containing, 25 mg, 37,5 mg, or 50 mg of risperidone.

2. WHAT RISPERDAL CONSTA IS USED FOR

RISPERDAL CONSTA is used to treat a group of disorders called psychoses (e.g. schizophrenia).
It is also used to treat bipolar disorder, formerly called manic depressive illness.
Both sets of conditions are brain function disorders.

3. BEFORE YOU RECEIVE RISPERDAL CONSTA

You should not be administered RISPERDAL CONSTA :

- If you are hypersensitive (allergic) to risperidone or any of the other ingredients. Allergy to RISPERDAL CONSTA can be recognised, for instance, by skin rash, itching, shortness of breath, or swollen face. If any of these occur, see your doctor.
- If you are under 18 years of age.

Tell your doctor or healthcare professional before being given the injection if :

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

- If you are taking furosemide. Studies in elderly patients with dementia have shown that RISPERDAL taken by itself or with furosemide, is associated with a

higher rate of death. Furosemide is a diuretic medicine which is sometimes used to treat high blood pressure.

- If you suffer with dementia you should not receive RISPERDAL CONSTA.

- Low blood pressure can result from using RISPERDAL CONSTA especially when taken with medications to treat high blood pressure. So, if you need to use both RISPERDAL CONSTA and medications to reduce blood pressure, consult your doctor.

- Tell your doctor if you or someone else in your family has a history of blood clots. Blood clots in the lungs and legs have been seen in patients taking RISPERDAL CONSTA. Blood clots in the lungs can be fatal.

- During long-term treatment, RISPERDAL CONSTA might cause involuntary twitching in the face. Should this happen, consult your doctor.

- A state of confusion, reduced consciousness, high fever or stiff muscles might occur. If this should happen, contact a doctor right away and tell him or her that you are receiving RISPERDAL CONSTA.

- As dangerously low numbers of a certain type of white blood cell needed to fight infection in your blood has been seen with patients taking RISPERDAL CONSTA, your doctor may check your white blood cell counts. Tell your doctor 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).

- High blood sugar has been reported. Contact your doctor if you experience symptoms, such as excessive thirst or urination or if you are diabetic inform your medical doctor.

- RISPERDAL CONSTA should be used with caution, if you have heart problems, particularly irregular heart rhythm, abnormalities in electrical activity of the heart, or if using medications that can change the heart's electrical activity.

- 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 taking RISPERDAL CONSTA.

Allergic reactions

Even if you have previously tolerated oral risperidone, very 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.

Weight gain

Try to eat moderately, since RISPERDAL CONSTA can cause weight gain.

Parkinson's disease, Lewy body dementia, or Neuroleptic Malignant Syndrome

If you are suffering from any of these disorders, inform your doctor. Medical supervision might be necessary while you receive RISPERDAL CONSTA and your dose may have to be adjusted.

Elderly people and people with impaired kidney or liver function

See “How to receive RISPERDAL CONSTA and how much”.

Pregnancy and Breastfeeding :

If you are pregnant or breastfeeding your baby, please consult your doctor, pharmacist or other healthcare professional for advice before taking this medicine. Shaking, muscle stiffness and/or weakness, sleepiness, agitation, breathing problems, or difficulty in feeding may occur in newborns, if a mother used RISPERDAL CONSTA in the last trimester of her pregnancy.

Do not breastfeed if you are receiving RISPERDAL CONSTA. Consult your doctor in this case.

Driving and using machinery :

RISPERDAL CONSTA may affect your alertness or driving ability. You are, therefore, advised not to drive or to operate machines before your doctor has assessed your personal sensitivity to RISPERDAL CONSTA.

Using other medicines with RISPERDAL CONSTA

Always tell your healthcare professional if you are taking other medicines. (This includes complementary or traditional medicines.)

RISPERDAL CONSTA can increase the effect of alcohol and medicines that reduce the ability to react ("tranquilizers”, narcotic painkillers, certain antihistamines, certain antidepressants). Do not drink alcohol and only take such medicines if your doctor prescribes them.

The following medicines may change the effect of RISPERDAL CONSTA. Therefore, inform your doctor if you start or stop taking any of these medicines:

- Medicines used to treat Parkinson's disease, such as dopamine agonists, e.g. levodopa.
- Medicines that increase the activity of the central nervous system (psychostimulants, such as methylphenidate)
- If you are taking medicines for high blood pressure, consult your doctor, as taking these medicines together with RISPERDAL CONSTA may cause the blood pressure to drop too low.
- RISPERDAL CONSTA should be used with caution when taking medications that may change the electrical activity of the heart, such as but not restricted to: medicines for malaria, heart rhythm disorders, allergies, other antipsychotics, antidepressants, water tablets or other medicines affecting body salts (sodium, potassium, magnesium).

Some medicines, when they are taken together with RISPERDAL CONSTA, may increase or decrease the level of RISPERDAL CONSTA in your blood. Therefore, tell your doctor if you start and/or stop taking any of the below medicines, since your doctor may need to change the dose.

Medicines that can increase the level of RISPERDAL CONSTA in your blood:

- Fluoxetine and paroxetine, medicines mainly used to treat depression;
- 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.

Medicines that can decrease the level of RISPERDAL CONSTA in your blood:

- Carbamazepine, a medicine mainly used for epilepsy or trigeminal neuralgia (severe pain attacks in the face);
- Rifampicin, a medicine for treating some infections.

Tell your doctor if you are taking furosemide.

The following medicines are unlikely to change the effect of RISPERDAL CONSTA:

- Cimetidine and ranitidine, two medicines used to reduce stomach acid, may slightly increase the level of RISPERDAL CONSTA in your blood, but they are unlikely to change the effect of RISPERDAL CONSTA.
- Erythromycin, an antibiotic, does not have an effect on the level of RISPERDAL CONSTA in the blood.
- Topiramate, a medicine used to treat epilepsy, does not have a significant effect on the level of RISPERDAL CONSTA in the blood.
- Galantamine and donezepil, medicines used to treat dementia, do not have an effect on RISPERDAL CONSTA.

RISPERDAL CONSTA is unlikely to change the effect of the following medicines:

- RISPERDAL CONSTA does not show an effect on lithium or valproate, two medicines used to treat mania, or on digoxin, a heart medication.

4. HOW TO RECEIVE RISPERDAL CONSTA

Do not share medicines prescribed for you with others

RISPERDAL CONSTA is given as an intramuscular injection in the buttock or upper shoulder every two weeks. Injections should be alternated between right and left sides, and should not be given intravenously.

Your doctor may prescribe oral risperidone for the first three weeks following your first injection.

Adults

The recommended dose is 25 mg every two weeks as an injection. A higher dose of 37,5 or 50 mg may be necessary. The maximum dose should not exceed 50 mg every two weeks. Your doctor may prescribe oral risperidone for the first three weeks following your first injection.

Elderly people

The recommended dose is 25 mg by injection every two weeks. Your doctor may prescribe oral risperidone for the first three weeks following your first injection.

People with impaired kidney or liver function

RISPERDAL CONSTA has not been studied in people with impaired kidney or liver function.

Children

RISPERDAL CONSTA has not been studied in children younger than 18 years.

If you are given more RISPERDAL CONSTA than you should :

In the event of overdosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison control center.

While overdose is less likely to occur with injections than with oral medication, information pertaining to oral is presented.

One or more of the following signs may occur: reduced consciousness, drowsiness, sleepiness, excessive trembling or excessive muscle stiffness, fast beating heart and low blood pressure. Cases of abnormal electrical conduction in the heart (QT prolongation) and convulsion have been reported. Overdose can happen if you are taking other medication with RISPERDAL. However, you should contact your doctor.

5. POSSIBLE SIDE EFFECTS

RISPERDAL CONSTA can have side effects.

Should you experience these side effects, please consult your doctor.

Not all side effects reported for RISPERDAL CONSTA are included in this leaflet.

Should your general health worsen or if you experience any untoward effects while taking RISPERDAL CONSTA, please consult your doctor, pharmacist or other health care professional for advice.

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 if 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 RISPERDAL CONSTA 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. 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.

- Are considering cataract surgery, a condition called intraoperative floppy iris syndrome (IFIS) can occur if you take or have taken RISPERDAL CONSTA. If you need to have cataract surgery, be sure to tell your eye doctor if you take or have taken this medicine.

FREQUENT SIDE EFFECTS ·

- Sleep disorder, irritability, decreased sexual drive, restlessness, feeling sleepy, or less alert.
- 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.
- Pneumonia, infection of the chest (bronchitis), sinus infection, feeling like you have the flu, common cold symptoms.
- Urinary tract infection.
- Anaemia.
- Increase blood prolactin (symptoms of high prolactin include in men breast swelling, difficulty in getting or maintaining erections, 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).
- High blood sugar, weight gain, increased appetite, weight loss, decreased appetite
- 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.
- 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.
- Swelling of the body, arms or legs, fever, weakness, fatigue (tiredness), chest discomfort.
- Pain.
- A reaction at the injection site, including itching, pain or swelling.
- Increased liver transaminases in your blood, increased GGT (a liver enzyme called gammaglutamyltransferase) in your blood.
- Fall.

LESS FREQUENT SIDE EFFECTS

- Ear infection.
- Eye infection, tonsillitis, fungal infection of the nails, infection of the skin, infection, 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).
- Sugar in the urine, diabetes or worsening of diabetes.
- High blood triglycerides (a fat), increased cholesterol in your blood.
- Elated mood (mania), confusion, inability to reach orgasm, nervousness, nightmares.

- Loss of consciousness, convulsion (fits), fainting.
- Restless urge to move parts of the body, balance disorder.
- 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), palpitations
- Low blood pressure upon standing.
- 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 discolouration, acne, flaky, itchy scalp or skin.
- Joint stiffness, joint swelling, muscle weakness, neck pain.
- Frequent passing of urine, inability to pass urine, pain when passing urine.
- Breast pain, breast discomfort, vaginal discharge.
- Chills, an increase in body temperature.
- Inappropriate secretion of a hormone that controls urine volume.
- Low blood sugar.
- Excessive drinking of water.
- Sleep walking.
- Sleep -related eating disorder.
- Not moving or responding while awake (catatonia).
- Problems with movement of your eyes, eye rolling, oversensitivity of the eyes to light.
- Increase in eosinophils (a type of white blood cell) in your blood.
- Trouble breathing during sleep (sleep apnea).
- Inflammation of the pancreas, a blockage in the bowels.

- Hives (or "nettle rash"), thickening of skin, dandruff, skin disorder, skin lesion.
- Breakdown of muscle fibers and pain in muscles (rhabdomyolysis).
- Yellowing of the skin and the eyes (jaundice).
- Increased insulin (a hormone that controls blood sugar levels) in your blood.
- Coma due to uncontrolled diabetes.
- Sudden loss of vision or blindness.
- Glaucoma (increased pressure within the eyeball), eyelid margin crusting.
- Enlargement of the glands in your breasts.
- A decrease in body temperature, coldness in arms and legs.
- Symptoms of drug withdrawal.

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist

6. STORING AND DISPOSING OF RISPERDAL CONSTA

Store all medicines out of reach of children.

- The entire dose pack should be stored in the refrigerator at 2 °C – 8 °C in the original package in order to protect from light.
  If refrigeration is unavailable, RISPERDAL CONSTA can be stored at temperatures below 25 °C for no more than 7 days before administration.
- Do not expose un-refrigerated product to temperatures above 25 °C.
- Do not use after the expiry date stated on the label.
- Return all unused medicines to your pharmacist
- Do not dispose of unused medicine in drains or sewerage systems (e.g.toilets)

7. PRESENTATION OF RISPERDAL CONSTA

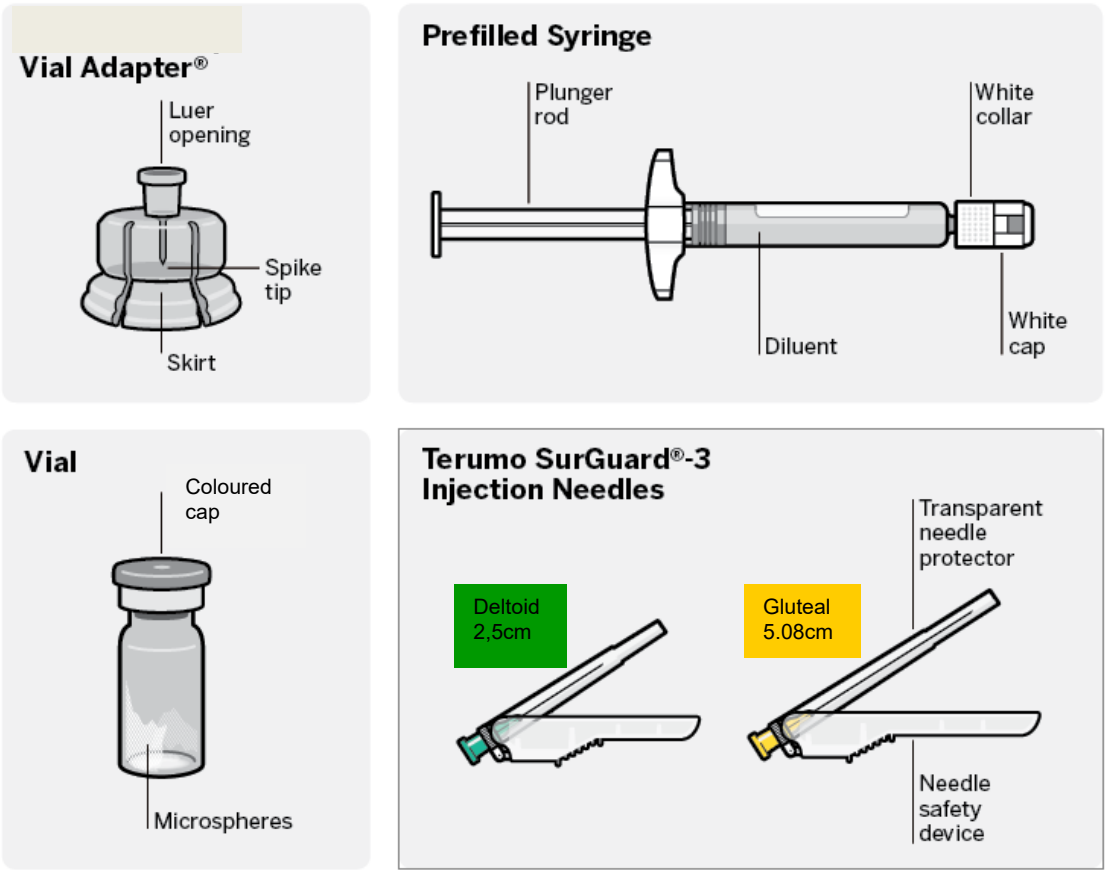
-One 5 mℓ vial containing RISPERDAL CONSTA extended release microspheres, powder for suspension for injection.

- One 3 mℓ prefilled syringe containing 2 mℓ diluent for RISPERDAL CONSTA.

- One Vial Adapter for reconstitution (referred as Vial Adapter).

- Two Terumo SurGuard® 3 Needles for intramuscular injection (a 21G UTW 2,5 cm safety needle with needle protection device for deltoid administration and a 20G TW 5,08 cm safety needle with Needle-Pro safety device for gluteal administration). ("Rx-only"=device to be sold with prescription only) medicines.

Dose pack contents



8. IDENTIFICATION OF RISPERDAL CONSTA

Clear, colourless, glass vial with a grey rubber stopper, tightly crimped, coloured flip-off cap* containing a white, free flowing powder, free from visible foreign material, suspending readily without clumping or visible foreign material.

* The colour of the flip-off cap is verified- the colour varies by dosage strengths as follows:

Pink: 25 mg risperidone per vial

Green: 37,5 mg risperidone per vial

Blue: 50 mg risperidone per vial

Pre-filled syringe of diluent for reconstitution.

Clear, colourless, aqueous solution free from visible foreign materials.

9. REGISTRATION NUMBERS

RISPERDAL CONSTA 25, 37,5 & 50 mg ;37/2.6.5/0142 – 0144

10. THE NAME, BUSINESS ADDRESS AND TELEPHONE NUMBER OF THE HOLDER OF THE CERTIFICATE OF REGISTRATION



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11. DATE OF PUBLICATION

- The date on the registration certificate of the medicine: 29 July 2005

- The date of the most recently revised patient information leaflet as approved by Advisory Clinical Committee: 02 May 2019