

PART III: CONSUMER INFORMATION

PrRISPERDAL CONSTA® risperidone powder for Injectable Prolonged-Release Suspension

This leaflet is Part III of a three-part “Product Monograph” published when RISPERDAL CONSTA® was approved for sale in Canada and is designed specifically for Consumers. This leaflet is a summary and will not tell you everything about RISPERDAL CONSTA®. Contact your doctor or pharmacist if you have any questions about the drug.

ABOUT THIS MEDICATION

What the medication is used for:

RISPERDAL CONSTA® belongs to a group of medicines called antipsychotic drugs.

RISPERDAL CONSTA® is used to treat the symptoms of schizophrenia and related psychotic disorders, as well as those of bipolar disorder.

Signs and symptoms of schizophrenia, include but are not limited to hallucinations (hearing or seeing things that are not there), delusions, unusual suspiciousness, or emotional withdrawal. Patients suffering from schizophrenia may also feel depressed, anxious or tense.

Signs and symptoms of bipolar mania include but are not limited to: high, elevated or irritable mood, feeling invincible or all powerful, inflated self-esteem, racing thoughts, easily losing your train of thought, overreaction to what you see or hear, misinterpretation of events, speeded-up activity, talking very quickly, talking too loudly, or talking more than usual, decreased need for sleep and poor judgment.

The doctor has prescribed RISPERDAL CONSTA®, to help relieve the symptoms that are bothering you/the patient you are caring for. Although RISPERDAL CONSTA® cannot cure the illness, it can keep the symptoms under control and reduce the risk of relapse as you/the patient you are caring for continue treatment.

What it does:

Antipsychotic medications affect the chemicals that allow communication between nerve cells (neurotransmitters). These chemicals are called dopamine and serotonin. Exactly how RISPERDAL CONSTA® works is unknown. However, it seems to readjust the balance of dopamine and serotonin.

When it should not be used:

RISPERDAL CONSTA® should not be given if an allergic reaction to risperidone, paliperidone, or any of the nonmedicinal ingredients of the product has occurred.

Symptoms of an allergic reaction may include: itching, skin rash, swelling of the face, lips or tongue, shortness of breath.

If you experience any of these symptoms/if these symptoms are experienced by the patient you are caring for, your doctor/the treating physician should be contacted immediately.

The safety and efficacy of RISPERDAL CONSTA® in children under the age of 18 have not been established.

What the medicinal ingredient is:

risperidone

What the nonmedicinal ingredients are:

The diluent contains polysorbate 20, sodium carboxymethylcellulose, disodium hydrogen phosphate dihydrate, citric acid anhydrous, sodium chloride, sodium hydroxide, and water for injection.

Risperidone is micro-encapsulated in a polylactide-co-glycolide.

What dosage forms it comes in:

RISPERDAL CONSTA® is available in 4 strengths, 12.5 mg (violet cap), 25 mg (pink cap), 37.5 mg (green cap) and 50 mg (blue cap) per vial.

WARNINGS AND PRECAUTIONS

Serious Warnings and Precautions

Increased Risk of Death in Elderly People with Dementia. Medicines like RISPERDAL CONSTA® can raise the risk of death in elderly people who have dementia. RISPERDAL CONSTA® is not approved for use in patients with dementia.

BEFORE starting RISPERDAL CONSTA® treatment, talk to your doctor if you/the patient you are caring for:

- have had serious allergic reactions to other medications, including oral risperidone or oral paliperidone. Even if you have not had a reaction to oral risperidone or oral paliperidone before, it can occur very rarely after receiving injections of RISPERDAL CONSTA®
- have a history of stroke, mini-strokes, high cholesterol or high blood pressure. Medicines like RISPERDAL CONSTA® can raise the risk of stroke in elderly people who have dementia. RISPERDAL CONSTA® is not approved for use in patients with dementia

- have had neuroleptic malignant syndrome (a disorder that causes you to have high fever and stiffness in your muscles)
- have had tardive dyskinesia (a disorder that causes you to have uncontrolled and repeated movements of the tongue, face or other body parts)
- have or are at risk for diabetes or high blood sugar or a family history of diabetes
- are pregnant, think you may be pregnant or planning to become pregnant
- are breast-feeding or planning to breast-feed
- have or have had prolonged and/or painful erection
- have or have ever had blackouts or seizures
- have a history of kidney or liver problems
- have a history of:
 - problems with the heart and/or blood vessels
 - any problems with the way your heart beats
- are being treated for high blood pressure
- are taking any medications that affect how your heart beats
- have had low white blood cell counts in your blood. Let your doctor know right away if you develop a fever or infection while being treated with RISPERDAL CONSTA®
- have high levels of cholesterol or fats (triglycerides) in your blood
- have, have a history of, or are at risk of:
 - sleep apnea (a sleep disorder where your breathing is interrupted during sleep)
 - sleep walking
 - sleep-related eating disorder
- are prone to hypotension (low blood pressure), have or have had a heart disease or heart disease treatment that makes you more likely to have low blood pressure or feeling dizzy or faint when you stand up from lying or sitting positions
- are at risk for developing blood clots. Risk factors include:
 - a family history of blood clots
 - being over the age of 65
 - smoking
 - being overweight
 - having a recent major surgery (such as hip or knee replacement)
 - not being able to move due to air travel or other reasons
 - taking oral birth control (“The Pill”)
- have Parkinson’s disease
- have Lewy body dementia
- have or have had breast cancer
- have pituitary tumours
- suffer from Alzheimer’s disease
- are feeling thirsty and unwell
- exercise strenuously. This kind of medication may interfere with your body’s ability to adjust to heat. You should avoid becoming overheated or dehydrated (for

example with vigorous exercise or exposure to extreme heat) while taking RISPERDAL CONSTA®

- are taking any other medicines (prescription or over-the-counter medicines, or natural health products)
 - drink alcoholic beverages or use drugs
 - are planning to have an operation on the eye(s). During surgery to treat the cloudiness of the lens in your eye(s) (known as cataract surgery):
 - the pupil (the black circle in the middle of your eye) may not increase in size as needed
 - the iris (the coloured part of the eye) may become floppy during surgery. This may lead to eye damage
- Tell your eye doctor you are taking this medicine.

Elderly Patients with Dementia

- Studies in elderly patients with dementia have shown that -RISPERDAL® taken by itself or with furosemide (a “water pill”) is associated with a higher rate of death (see **Serious Warnings and Precautions Box**).

Tell your doctor if you are taking furosemide. This drug can be used to treat:

- high blood pressure
- some heart problems
- swelling of parts of the body caused by the build-up of too much fluid.

- In elderly patients with dementia:
 - a sudden change in mental state
 - sudden weakness or numbness of the face, arms or legs, especially on one side of the body
 - slurred speech
 - vision problems
- have been seen.

If any of these should occur, even for a short period of time, seek medical attention right away.

If you are taking blood pressure medication

Low blood pressure can result from using RISPERDAL CONSTA® together with medications used to treat high blood pressure. If you need to use both RISPERDAL CONSTA® and medications used to reduce blood pressure, consult your doctor.

Effects on newborns

You should not take RISPERDAL CONSTA® while you are pregnant or if you are planning on becoming pregnant unless you have talked to your doctor about it.

If you took RISPERDAL CONSTA® at any time while you were pregnant or if you took it before you became pregnant, the following symptoms may happen in your newborn baby:

- shaking
- stiffness in their muscles and/or weakness

- sleepiness
- agitation
- breathing problems
- difficulty feeding

Get medical help right away if your newborn baby has any of these symptoms.

In some cases, babies born to a mother taking risperidone during pregnancy have experienced symptoms that are severe and require the newborn to be hospitalized.

Other cautions

Driving and using machines: Do not drive or operate machinery until you know how you respond to RISPERDAL CONSTA®. Some people experience drowsiness or blurred vision while taking RISPERDAL CONSTA®.

Falls: Feeling sleepy, a fall in blood pressure when you stand up from sitting or lying down, vision and speech problems have been reported with the use of antipsychotic drugs. This can lead to falls that may cause fractures or other fall-related injuries. Certain medications, diseases or conditions can make this worse.

Weight gain: Weight gain has been seen in patients who are taking antipsychotic drugs. Your doctor may monitor your body weight when you are taking RISPERDAL CONSTA®.

Blood tests: Your doctor should do blood tests before you start taking RISPERDAL CONSTA®. They will check your blood sugar levels, and for those with certain risk factors, the level of white blood cells in your blood. Your doctor should continue to check your blood for as long as you are being treated with RISPERDAL CONSTA®.

It is important for the doctor to have all the above information before prescribing treatment and dosage. This list should be carefully reviewed by you/the caregiver and discussed with the doctor.

INTERACTIONS WITH THIS MEDICATION

Inform all doctors, dentists and pharmacists who are treating you that you are being treated with RISPERDAL CONSTA®.

Inform them if you are taking or are planning to take any other medicine, including other prescription or over-the-counter medications and natural health products. They will tell you which medicines you can take with RISPERDAL CONSTA®.

RISPERDAL CONSTA® can increase the effect of alcohol and medicines that reduce the ability to react (“tranquilizers”, narcotic painkillers, certain antihistamines, certain antidepressants). It is recommended that you DO NOT drink

alcohol when you are taking RISPERDAL CONSTA®. You should only take these other medicines when they have been prescribed by your doctor.

Some medicines, when they are taken together with RISPERDAL®, may increase or decrease the level of RISPERDAL® 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:

- Dopamine agonists, e.g., levodopa (a drug used to treat Parkinson’s disease), as these may decrease the effect of RISPERDAL CONSTA®. Also RISPERDAL CONSTA® can affect how drugs used to treat Parkinson’s disease work.
- Phenothiazines and some heart medications (e.g., medication for high blood pressure, antiarrhythmics, or beta-blockers), as these may interact with RISPERDAL CONSTA® to cause your 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 (QT prolongation), 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).
- Carbamazepine and topiramate (drugs used to treat seizures), as these may change the effect of RISPERDAL CONSTA®.
- PROZAC® (fluoxetine), PAXIL® (paroxetine) (antidepressants) and CLOZARIL® (clozapine) (antipsychotic), as these may increase the level of RISPERDAL CONSTA® in your blood.
- LASIX® (furosemide): Studies in elderly patients with dementia have shown that taking RISPERDAL® along with furosemide, a medicine which is sometimes used to treat high blood pressure, some heart problems, or to treat swelling of parts of the body caused by the build-up of too much fluid, is associated with an increased rate of death (see **WARNINGS AND PRECAUTIONS**).
- Itraconazole and ketoconazole, medicines for treating fungal infections.
- Certain medicines used in the treatment of HIV/AIDS, such as NORVIR® (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.
- Rifampicin, a medicine for treating some infections.
- RISPERDAL CONSTA® should be used with caution with medicines that increase the activity of the central nervous system (psychostimulants such as methylphenidate).

PROPER USE OF THIS MEDICATION

Usual dose:

The usual dose is 25 mg given every two weeks by intramuscular injection either in the buttock or arm by your doctor. For some patients, a lower dose of 12.5 mg might be used. Injections should be alternated between right and left sides and should not be given intravenously. If you have never taken any form of RISPERDAL®, your physician may give you oral RISPERDAL® before beginning treatment with RISPERDAL CONSTA®.

Overdose:

If you have been given too much RISPERDAL CONSTA®, contact your healthcare professional, hospital emergency department or regional Poison Control Centre immediately, even if there are no symptoms.

In overdose, one or more of the following signs may occur:

- reduced consciousness
- sleepiness
- excessive trembling
- excessive muscle stiffness
- fast beating heart
- irregular heartbeat or other symptoms of an irregular heartbeat, such as lightheadedness or fainting
- dizziness or lightheadedness when standing up

Cases of abnormal electrical conduction in the heart (QT prolongation) and convulsions have been reported.

Missed dose:

If you miss an appointment, you should contact your doctor right away to let him or her know you missed your injection. Your doctor will then advise you when to come next for your scheduled appointment.

SIDE EFFECTS AND WHAT TO DO ABOUT THEM

These are not all the possible side effects you may feel when taking RISPERDAL CONSTA®. If you experience any side effects not listed here, contact your healthcare professional.

Side effects that may occur very commonly are common cold symptoms, difficulty falling or staying asleep, depression, anxiety, trembling, decreased motor function or activity such as slight muscle stiffness, increased saliva and/or drooling, and headache.

Side effects that may occur commonly include: pneumonia, urinary tract infection, feeling like you have the flu, anemia, sleep disorder, irritability, weight loss, uncontrollable movements of the face or body, rigid muscles, slowness of movement and muscle stiffness or spasm, tremor, blurry vision, faster heart rate, low blood pressure, high blood pressure, abdominal pain, nausea/vomiting, constipation, diarrhea, indigestion, dry mouth, muscle spasms, loss of urine, swelling of the body, arms or legs, weakness, fatigue, increased liver transaminases in your blood, and a reaction at the injection site including itching, pain or swelling.

RISPERDAL CONSTA® can raise your levels of a hormone called “prolactin”. This is measured with a blood test.

Symptoms may include:

- In men:
 - swelling in the breast
 - difficulty in getting or maintaining an erection or other sexual dysfunction.
- In women
 - discomfort in the breasts
 - leaking of milk from the breasts (even if not pregnant)
 - missing your menstrual period or other problems with your cycle

If you have high levels of prolactin and a condition called hypogonadism you may be at an increased risk of breaking a bone due to osteoporosis. This occurs in both men and women.

High blood sugar has been reported. See your doctor if you experience symptoms, such as excessive thirst or urination.

Uncommon side effects may include: sugar in the urine, diabetes mellitus or worsening of diabetes, high blood triglycerides (a fat), increased cholesterol in your blood, mania, a restless urge to move parts of your body, concentration difficulties, nervousness, itching, joint swelling, swelling of the ankles, heartbeat irregularities and changes in body temperature .

RISPERDAL CONSTA® may cause sudden dizziness or lightheadedness (symptoms of postural hypotension). You/the

patient you are caring for should not rise rapidly after having been sitting or lying for prolonged periods, especially when you start taking RISPERDAL CONSTA®.

In rare cases, the following may happen: low blood sugar, and irregular heartbeat.

Lack of bowel muscle movement that causes blockage may occur very rarely.

SERIOUS SIDE EFFECTS AND WHAT TO DO ABOUT THEM			
Symptom/effect	Call your doctor or pharmacist		Stop taking drug and seek immediate medical emergency help
	Only if severe	In all cases	
Common			
Skin rash on its own		✓	
Dystonia: twisting movements that you cannot control, and can affect posture or the face, including eyes, mouth, tongue or jaw		✓	
Uncommon			
Seizure (i.e., loss of consciousness with uncontrollable shaking)			✓
Tardive Dyskinesia: Muscle twitching or abnormal movements of the face or tongue or body		✓	
Severe allergic reaction: fever, itching, skin rash, swelling of the mouth, face, lips or tongue, shortness of breath, and sometimes a drop in blood pressure (amounting to an “anaphylactic reaction”)			✓
Dysphagia: Difficulty swallowing that can cause food or liquids to get into your lungs		✓	
Rare			

Inflammation of the pancreas: severe abdominal pain, fever, nausea, vomiting			✓
Jaundice: yellowing of the skin and eyes, dark urine			✓
Rhabdomyolysis: Very dark (“tea coloured”) urine, muscle tenderness and/or aching			✓
Blood clots: swelling, pain and redness in an arm or leg that can be warm to touch. You may develop sudden chest pain, difficulty breathing and heart palpitations.		✓	
A state of confusion, reduced consciousness, high fever, or pronounced muscle stiffness			✓
Decreased White Blood Cells: infections, fatigue, aches, pains and flu-like symptoms			✓
Very Rare			
Life-threatening complications of uncontrolled diabetes such as shortness of breath, confusion and loss of consciousness			✓
Marked changes in body temperature (generally as a result of several factors together including extreme heat or cold).			✓
Sudden loss of vision or blindness			✓
Priapism: long-lasting (greater than 4 hours in duration) and painful erection of the penis			✓
Sudden change in mental state or sudden weakness or numbness of the face, arms or legs, especially on one side, slurred speech or vision problems, even for a short period of time			✓

Bruise easily, excessive bleeding		✓	
Injection site reactions that may require medical attention, including accumulation of pus caused by bacterial infection, deep skin infection, a sac or lump under the skin, accumulation of blood or severe bruise, dead cells or tissues, and skin ulcer		✓	
Symptoms of muscle breaking down such as pain, weakness and swelling of the muscles – can be detected by blood test/can lead to kidney failure			✓
Serious Allergic reactions even if you have previously tolerated oral risperidone or oral paliperidone; symptoms include rash, swelling of your throat, itching or problems breathing. These may be signs of a serious allergic reaction.			✓
Catatonia: unable to move or respond while awake.		✓	

If you have a troublesome symptoms or side effect that is not listed here or becomes bad enough to interfere with your daily activities, talk to your healthcare professional.

HOW TO STORE IT

Store RISPERDAL CONSTA® in its original package in the refrigerator at 2°C–8°C, protected from light. If refrigeration is not available, store at temperatures not exceeding 25°C and protected from light for no more than 7 days. Do not expose unrefrigerated product to temperatures above 25°C.

Keep RISPERDAL CONSTA® out of the sight and reach of children.

The expiry date for RISPERDAL CONSTA® is printed on the package. Do not use the medicine in the package after this date.

REPORTING SIDE EFFECTS

You can help improve the safe use of health products for Canadians by reporting serious and unexpected side effects to Health Canada. Your report may help to identify new side effects and change the product safety information.

3 ways to report:

- Online at MedEffect®
(<https://www.canada.ca/en/health-canada/services/drugs-health-products/medeffect-canada/adverse-reaction-reporting.html>);
 - By calling 1-866-234-2345 (toll-free);
 - By completing a Consumer Side Effect Reporting Form and sending it by:
 - Fax to 1-866-678-6789 (toll-free), or
 - Mail to: Canada Vigilance Program
Health Canada, Postal Locator
1908C
Ottawa, ON
K1A 0K9
- Postage paid labels and the Consumer Side Effect Reporting Form are available at MedEffect® (<https://www.canada.ca/en/health-canada/services/drugs-health-products/medeffect-canada/adverse-reaction-reporting.html>).

NOTE: Contact your health professional if you need information about how to manage your side effects. The Canada Vigilance Program does not provide medical advice.

MORE INFORMATION

For questions, concerns, or the Product Monograph go to www.janssen.com/canada or contact the manufacturer, Janssen Inc., at: 1-800-567-3331 or 1-800-387-8781.

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