

RISPERDAL CONSTA®

INTRAMUSCULAR INJECTION

Risperidone

Consumer Medicine Information

What is in this leaflet

This leaflet contains important information about RISPERDAL CONSTA. It does not contain all of the available information. It does not take the place of talking to your doctor or pharmacist.

If you have any concerns about using RISPERDAL CONSTA, ask your doctor, pharmacist or nurse. Your doctor and pharmacist have more information.

Keep this leaflet with your RISPERDAL CONSTA. You may need to read it again.

What RISPERDAL CONSTA is used for?

RISPERDAL CONSTA is used to treat symptoms of schizophrenia and other types of related psychoses. These are disorders related to thought, feeling and/or action.

RISPERDAL CONSTA is also used to treat bipolar disorder to prevent or delay mood swings which consist of alternating periods of high (manic) or elevated mood with periods of depression. During the manic episodes you may feel very excited, elated, agitated, enthusiastic, or hyperactive, or have poor judgment including disruptive or aggressive behaviours. During the episodes of depression you may experience sadness, low energy, lack of motivation, feelings of guilt and worthlessness, and changes in sleep or appetite.

RISPERDAL CONSTA helps to correct a chemical imbalance in the brain associated with these conditions.

RISPERDAL CONSTA has been approved for the uses mentioned above. However, your doctor may prescribe this medicine for another use. If you want more information, ask your doctor.

RISPERDAL CONSTA is not addictive.

Before you use RISPERDAL CONSTA

When you must not use it

Do not use RISPERDAL CONSTA:

- if you know you are allergic to any of its ingredients (signs of allergy include skin rash, itching, shortness of breath, and/or swollen face - see the last section of this leaflet for a list of ingredients).
- if the packaging is torn or shows signs of having been tampered with.
- to treat any other complaints unless your doctor says it is safe to do so.

Before you start to use it

RISPERDAL CONSTA should be used with caution in some patients.

1. Tell your doctor if you have or have ever had any medical conditions, especially the following:

- heart or blood vessel diseases, including low blood pressure. Low blood pressure can result from using RISPERDAL CONSTA together 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. RISPERDAL CONSTA should be used with caution, and only after consultation with your doctor, 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.
- dehydration
- kidney or liver problems
- parkinson's disease (a disease of the brain affecting movement)
- dementia or Lewy body dementia
- low blood sugar
- sugar in the urine
- epilepsy, seizures or fits
- restlessness or difficulty sitting still
- intraoperative iris syndrome (a complication that may occur during cataract extraction)
- suicide
- breast discomfort
- breast cancer
- disease of the pituitary gland
- Neuroleptic Malignant Syndrome (a serious reaction to some medicines, consisting of a sudden increase in body temperature, extremely high blood pressure and severe convulsions)

- tardive dyskinesia (a reaction to some medicines, seen as uncontrollable twitching or jerking movements of the arms and legs)
- diabetes
- blood clots
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.
- low white blood cell count
As dangerously low numbers of certain types of white blood cells needed to fight infection in your blood has been seen very rarely 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).

2. Tell your doctor if:

- you are pregnant or are planning to become pregnant
Shaking, muscle stiffness and difficulty in feeding, all of which are reversible, may occur in newborns, if a mother used RISPERDAL CONSTA in the last trimester of her pregnancy.
- you are breast feeding

Your doctor will advise you whether or not you should use RISPERDAL CONSTA.

3. Other medicines and alcohol

RISPERDAL CONSTA can increase the effect of alcohol and other medicines which slow your reactions.

Tell your doctor if you are taking

- sleeping tablets
- tranquillisers
- strong painkillers
- antihistamines
- carbamazepine, a drug mainly used for epilepsy or trigeminal neuralgia (severe pain attacks in the face) may decrease the level

of RISPERDAL CONSTA in your blood.

- frusemide, a diuretic drug

Tell your doctor if you have ever taken medicines for depression. In particular, fluoxetine and paroxetine may increase the level of RISPERDAL in your blood. So tell your doctor if you start and/or stop taking fluoxetine or paroxetine.

- The following medicines do not have an effect on RISPERDAL: erythromycin (antibiotic), galantamine and donepezil (used to treat dementia), lithium or valproate (used to treat mania), digoxin (a heart drug), topiramate (used to treat epilepsy or migraine), itraconazole and ketoconazole (used to treat fungal infection), cimetidine and ranitidine (used to reduce stomach acid).

Tell your doctor if you are taking medicines for:

- Parkinson's disease or a tremor
- epilepsy
- diuretics
- other medicines for your heart or blood pressure.

You should not drink alcohol while using RISPERDAL CONSTA.

Your doctor or pharmacist has more information on the medicines to avoid, or to be careful of, while you are using RISPERDAL CONSTA.

4. Elderly people

Elderly people should receive the lowest dose (25mg) of RISPERDAL CONSTA (see "How to use it").

5. Children and Adolescents

There is no experience with RISPERDAL CONSTA in patients under 18 years of age.

Using it for the first time

Treatment with RISPERDAL CONSTA will not be started until it is known that you can tolerate Risperdal treatment by mouth (tablets or oral solution).

At the start of treatment you may have a fall in blood pressure making you feel dizzy on standing up, or your heart may beat faster. These should go away after a few days. Tell your doctor if they continue or worry you.

Using RISPERDAL CONSTA

How to use it

RISPERDAL CONSTA should be given only after the powder has been mixed with the diluent (liquid in the syringe) supplied in the package.

The information for your doctor or nurse on the right way to reconstitute (make up) RISPERDAL CONSTA is included in the package.

After it has been made up, RISPERDAL CONSTA should be injected in the arm or buttock every two weeks. Next time the injection will be given into the other arm or buttock, and so on. Injection is not to be given intravenously.

The usual dose of RISPERDAL CONSTA is 25mg once every two weeks. However, your doctor might decide to administer a higher dose of 37.5mg or 50mg. Your doctor will decide on the dose of RISPERDAL CONSTA that is right for you.

Because risperidone is released gradually into your body, you will need an injection only every two weeks. During the first three weeks of treatment additional risperidone tablets or liquid, which can be taken by mouth, must be used, because the first injection will not start to work straight away. Your doctor will explain this to you.

Later, depending on how well the treatment is working, your doctor may decide to further adjust the dose of RISPERDAL CONSTA or to add oral RISPERDAL (tablets or solution) for a short time.

Do not stop your treatment just because you feel better. If you have to stop RISPERDAL CONSTA on the advice of your doctor, it is best to do it gradually. Stopping treatment suddenly may cause effects such as feeling sick, vomiting, sweating, sleeplessness, muscle stiffness, or jerky movements, or your original medical problem may come back.

Elderly people should receive the lowest dose (25mg) of RISPERDAL CONSTA.

Patients with impaired kidney and liver function.

RISPERDAL CONSTA has not been studied in patients whose kidney or liver is not working properly. Use in such patients should be with caution, a starting dose of 0.5mg twice-daily oral risperidone is recommended during the first week. In the second week 1mg twice daily or 2mg once daily can be given. If a daily total oral dose of at least 2mg is well tolerated (i.e. the drug does not upset you), an injection of RISPERDAL CONSTA can be administered every 2 weeks.

If you forget to use RISPERDAL CONSTA

- If you forget to use RISPERDAL CONSTA, contact your doctor or nurse as soon as possible.

Overdose

If you think you or anybody else has taken too much RISPERDAL CONSTA, contact your doctor, pharmacist or the Poisons Information Centre who will advise you what to do.

You can contact the Poisons Information Centre by dialling 13 11 26 in Australia, or 0800 POISONS or 0800 764 766 in New Zealand.

Signs of overdose may include drowsiness, sleepiness, excessive trembling, excessive muscle stiffness, increased heart rate, very low blood pressure causing fainting or unconsciousness.

While you are using RISPERDAL CONSTA

Things you must do

- Always follow your doctor's instructions carefully, and seek your doctor's advice before changing or stopping treatment. Your doctor will be happy to discuss any questions you may have with your treatment. Remember, this medicine has been prescribed for you only.
- Tell all doctors, dentists and pharmacists who are treating you, that you are using RISPERDAL CONSTA.
- If you become pregnant while using RISPERDAL CONSTA, tell your doctor.
- Pre-menopausal women should tell their doctor if they do not have a period for more than six months while using RISPERDAL CONSTA, even if they are not pregnant.

Things to be careful of

- **Do not drink alcohol.** RISPERDAL CONSTA can increase the effects of alcohol.
- Ask your doctor before taking any other medicines. RISPERDAL CONSTA can increase the effects of medicines which slow your reactions. Always ask your doctor or pharmacist before taking other medicines. These include herbal treatments and those bought in a pharmacy or supermarket.
- Be careful driving or operating machinery until you know how RISPERDAL CONSTA affects you. RISPERDAL CONSTA may cause dizziness or light-headedness in some people, especially after the first dose. Make sure you know how you react to RISPERDAL CONSTA before you drive a car, operate

machinery, or do anything else that could be dangerous if you are dizzy.

- Avoid excessive eating as there is a possibility of weight gain when using RISPERDAL CONSTA.

Side effects

All medicines can have side effects. Sometimes they are serious, but most of the time they are not.

RISPERDAL CONSTA is generally well tolerated and side effects are often hard to distinguish from the disease symptoms. You may need medical treatment if you get some of the side effects.

Tell your doctor as soon as possible if you do not feel well while you are using RISPERDAL CONSTA.

Below is a list of possible side effects you could get while using RISPERDAL CONSTA:

- sleeplessness
- agitation
- anxiety
- headache
- trembling
- excessive saliva
- blocked nose
- muscle stiffness
- restlessness in the legs
- fall in blood pressure, particularly on standing. This will be apparent to you as light-headedness or dizziness that passes after a few seconds or after sitting down again.
- fast heart rate
- weight gain
- decreased or increased appetite

Although these effects are generally not harmful, contact your doctor if they bother you too much.

The following may occur less often:

- drowsiness, tiredness, difficulty in concentrating, somnolence, usually mild and short lasting may occur more often in children than in adults

- blurred vision
- dizziness
- indigestion, nausea, abdominal pain, constipation
- sexual function disturbances - erectile dysfunction, problems with ejaculation, decreased sexual drive
- some loss of bladder control
- blockage in the bowel
- excessive thirst
- during a long treatment, twitching of the tongue, face, mouth and jaws can occur. Should this happen contact your doctor.
- in the early stages of treatment, in some people, blood pressure may decrease slightly and the heart beat increase resulting in dizziness. This usually goes away after a few days. (See "Using it for the first time").
- after using RISPERDAL CONSTA for a long time, some women may experience breast enlargement or get a discharge from the breasts. They may also experience irregular or heavy periods or absence of their periods. In men, breasts may enlarge slightly.

The following may occur rarely:

- Oversensitivity (allergy). (See "When you must not use it").
- In extremely rare cases, significant changes in body temperature may occur. This rise or fall in temperature is caused by a combination of several factors such as extreme cold or heat. Call your doctor if this happens.
- In elderly patients with dementia, sudden weakness or numbness of the face, arms or legs, especially on one side, instances of slurred speech and stroke have been seen. If any of these should occur, even for a short period of time, seek medical attention right away.
- In very rare cases, high blood sugar has been reported. The symptoms of high blood sugar may be the need to urinate more often or feeling thirsty all the

time. Contact your doctor if you experience any of these symptoms.

- Swelling of injection site.

IMPORTANT: If you experience high fever, stiff muscles, fast breathing, abnormal sweating or decreased mental alertness, contact your doctor immediately. Your body may not be reacting properly to the medicine.

Do not hesitate to report any other side effects to your doctor or pharmacist.

After using RISPERDAL CONSTA

Storage

Keep the entire pack of RISPERDAL CONSTA in a refrigerator (between 2 and 8°C).

- Do not store it or any medicines in the bathroom or near a sink. Heat and dampness can destroy some medicines.
- Keep it where young children cannot reach it.
- Do not use RISPERDAL CONSTA beyond the date (month and year) printed on the pack after the letters "EXP", even if it has been stored properly. Medicines cannot be stored indefinitely.

Disposal

Once you have finished using RISPERDAL CONSTA, ask your pharmacist what to do with any unused medicine.

Product description

What it looks like

RISPERDAL CONSTA is available in vials (small bottles) which contain different amounts of risperidone. The

package contains everything required to reconstitute and administer the product.

- A vial with white powder contains the RISPERDAL CONSTA Prolonged Release Powder.
- A syringe with diluent, with which the powder is mixed.
- Vial Adapter.
- Safety needles.

Ingredients

The active ingredient in RISPERDAL CONSTA is risperidone, which is present in amounts of either 25mg, 37.5mg or 50mg in an injection of RISPERDAL CONSTA.

The powder is made from a 7525 DL JN1 poly-(d/l-lactide-co-glycolide) polymer called polyglactin. A polymer is a small particle made up of many smaller, similar particles bound together. Risperidone is attached to this polymer and then slowly released from it once it has been injected into the body. The diluent contains polysorbate 20, carmellose sodium, dibasic sodium phosphate dihydrate, citric acid anhydrous, sodium chloride, sodium hydroxide and water for injections.

Sponsor

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NZ Office: Auckland, New Zealand
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Registration Numbers

RISPERDAL CONSTA 25mg -
AUST R 81489
RISPERDAL CONSTA 37.5mg -
AUST R 81490
RISPERDAL CONSTA 50mg -
AUST R 81491

This leaflet was prepared in January 2016.

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Cilag Pty Ltd.