

RISPERDAL CONSTA®

Consumer Medicine Information (CMI) summary

The [full CMI](#) on the next page has more details. If you are worried about using this medicine, speak to your doctor or pharmacist.

1. Why am I using RISPERDAL CONSTA?

RISPERDAL CONSTA contains the active ingredient risperidone. RISPERDAL CONSTA is used to treat symptoms of schizophrenia and other types of related psychoses. It 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.

For more information, see Section [1. Why am I using RISPERDAL CONSTA?](#) in the full CMI.

2. What should I know before I use RISPERDAL CONSTA?

Do not use if you have ever had an allergic reaction to risperidone or any of the ingredients listed at the end of the CMI.

Talk to your doctor if you have any other medical conditions, have an eye surgery planned, take any other medicines, or are pregnant or plan to become pregnant or are breastfeeding.

For more information, see Section [2. What should I know before I use RISPERDAL CONSTA?](#) in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with RISPERDAL CONSTA and affect how it works.

A list of these medicines is in Section [3. What if I am taking other medicines?](#) in the full CMI.

4. How RISPERDAL CONSTA is given?

RISPERDAL CONSTA will be given to you by injection by a healthcare professional. Your doctor will decide on the dose of RISPERDAL CONSTA that is right for you.

More instructions can be found in Section [4. How RISPERDAL CONSTA is given?](#) in the full CMI.

5. What should I know while using RISPERDAL CONSTA?

Things you should do	- Remind any doctor, dentist or pharmacist you visit that you are using RISPERDAL CONSTA. - If you are pre-menopausal, tell your doctor if you do not have a period for more than six months while using RISPERDAL CONSTA, even if you are not pregnant. - Tell your doctor immediately if you notice any involuntary movements of the tongue, mouth, cheeks or jaw which may progress to the arms and legs. - Be careful during strenuous exercise or exposure to extreme heat. Try to drink plenty of water.
Things you should not do	Do not miss an injection or stop the treatment without consulting your doctor first.
Driving or using machines	- Avoid driving or operating machinery until you are sure RISPERDAL CONSTA does not affect your alertness. - RISPERDAL CONSTA may cause dizziness or light-headedness in some people, especially after the first dose.
Drinking alcohol	Do not drink alcohol. RISPERDAL CONSTA can increase the effects of alcohol.

For more information, see Section [5. What should I know while using RISPERDAL CONSTA?](#) in the full CMI.

6. Are there any side effects?

Common side effects include difficulty in thinking, working or carrying out your usual daily activities, muscle, joint, nerve or movement changes, behavioural changes. Serious side effects include serious allergic reactions, heart or blood pressure problems, lung problems, diabetes, body temperature changes, involuntary movements, severe or life-threatening rash with blisters and peeling skin, mini-strokes.

For more information, including what to do if you have any side effects, see Section [6. Are there any side effects?](#) in the full CMI.

RISPERDAL CONSTA®

Active ingredient(s): *Risperidone*

Consumer Medicine Information (CMI)

This leaflet provides important information about using RISPERDAL CONSTA. **You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about using RISPERDAL CONSTA.**

Where to find information in this leaflet:

1. [Why am I using RISPERDAL CONSTA?](#)
2. [What should I know before I use RISPERDAL CONSTA?](#)
3. [What if I am taking other medicines?](#)
4. [How RISPERDAL CONSTA is given?](#)
5. [What should I know while using RISPERDAL CONSTA?](#)
6. [Are there any side effects?](#)
7. [Product details](#)

1. Why am I using RISPERDAL CONSTA?

RISPERDAL CONSTA contains the active ingredient **risperidone**. RISPERDAL CONSTA belongs to a group of medicines called antipsychotic agents.

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.
- **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.

2. What should I know before I use RISPERDAL CONSTA?

Warnings

Do not use RISPERDAL CONSTA if:

- you are allergic to risperidone, or any of the ingredients listed at the end of this leaflet.
- Always check the ingredients to make sure you can use this medicine.

Check with your doctor if you:

- **have any other medical conditions, especially the following:**

- o heart problems, particularly irregular heart rhythm, abnormalities in electrical activity of the heart, high or low blood pressure, or you've had a heart attack or stroke in the past or heart failure.
- o unusual, excessive sweating or diarrhoea, dehydration or problems with your body temperature regulation
- o kidney or liver problems
- o you are prone to dizziness when standing up from lying or sitting position
- o Parkinson's disease (a progressive movement and thinking disorder that tends to affect older people)
- o dementia or Lewy body dementia - older people suffering dementia may be at increased risk of stroke or death with RISPERDAL CONSTA.
- o sugar diabetes - unusual thirst, tiredness, blurred vision, upset stomach or need to urinate are common signs of high blood sugars
- o epilepsy, seizures or fits
- o continuous and/or painful erections (called 'priapism')
- o involuntary movements or unusual restlessness or difficulty sitting still
- o suicidal thoughts or past suicide attempts
- o low blood potassium levels (hypokalaemia)
- o breast cancer
- o cancer of the pituitary gland
- o Neuroleptic Malignant Syndrome (a serious reaction to some medicines that causes sudden increase in body temperature, very fast heartbeat, extremely high or low blood pressure and severe muscle stiffness or fits)
- o Tardive dyskinesia (a reaction to some medicines with uncontrollable twitching or jerking movements of the tongue, face, mouth, jaw, arms and legs)
- o 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 can occur with RISPERDAL CONSTA. Blood clots in the lungs can result in death
- o low white blood cell count - if you have low numbers of some white blood cells, your risk of contracting an infection or developing a fever is increased with RISPERDAL CONSTA).

- **you have any eye surgery planned.**

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 this medicine.

Your doctor will need to assess whether you are at risk of a surgical complication (called Intraoperative Floppy Iris Syndrome). You may be recommended to stop your RISPERDAL CONSTA temporarily prior to your eye surgery.

- **You will be in a hot environment or do a lot of vigorous exercise**

RISPERDAL CONSTA may make you sweat less, causing your body to overheat.

- take any medicines for any other condition.

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them. See additional information under Section [6. Are there any side effects?](#)

Pregnancy and breastfeeding

Check with your doctor if you are pregnant or intend to become pregnant.

Your doctor will advise you whether you should take RISPERDAL CONSTA.

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.

Talk to your doctor if you are breastfeeding or intend to breastfeed.

As RISPERDAL CONSTA is excreted in breast milk, it is recommended that you do not breastfeed while using this medicine.

Children and adolescents

RISPERDAL CONSTA cannot be recommended for use in children and adolescents under 18 years at the present time as there is no experience with the product in this group.

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.

3. What if I am taking other medicines?

Tell your doctor or pharmacist if you are taking any other medicines, including any medicines, vitamins or supplements that you buy without a prescription from your pharmacy, supermarket or health food shop.

Some medicines may interfere with RISPERDAL and affect how it works. In particular,

- RISPERDAL CONSTA can increase the effects of alcohol and medicines that reduce the ability to react (e.g., sleeping tablets, "tranquillisers", strong painkillers, certain antihistamines, certain antidepressants). Do

not drink alcohol and only take such medicines if your doctor prescribes them.

- some medicines for treating Parkinson's disease, (dopamine agonists, e.g. levodopa).
- medicines that increase the activity of the central nervous system (psychostimulants such as methylphenidate).
- other medicines to treat mental illness or psychotic conditions such as phenothiazines
- 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).
- taking RISPERDAL CONSTA with furosemide, a medicine used to treat high blood pressure, some heart problems or to treat swelling parts of the body caused by the build up of too much fluid. There is an increased risk of side effects or death in older people if frusemide is also taken with RISPERDAL CONSTA.

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 include:

- medicines to treat depression, and various anxiety disorders, such as fluoxetine and paroxetine
- medicines to treat fungal infections such as itraconazole and ketoconazole
- certain medicines to treat HIV/AIDS, such as ritonavir
- medicine used to treat high blood pressure and/or abnormal heart rhythm, verapamil
- medicines to treat depression and other psychiatric disorders, sertraline and fluvoxamine

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

- medicine mainly used for epilepsy or trigeminal neuralgia (severe pain attacks in the face), carbamazepine
- medicine for treating some bacterial infections such as rifampicin.

Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect RISPERDAL CONSTA.

4. How RISPERDAL CONSTA is given?

How much is given

RISPERDAL CONSTA is a medicine designed to gradually release the active ingredient in your body so that you do not have to take this medicine every day.

The usual dose of RISPERDAL CONSTA is 25mg once every two weeks. Your doctor will decide on the dose of RISPERDAL CONSTA that is right for you.

Patients with kidney and liver problems

RISPERDAL CONSTA has not been studied in patients whose kidney or liver is not working properly. Your doctor will decide the dose suitable for you. 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.

When is it given

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.

How it is given

RISPERDAL CONSTA will be given to you by injection by a healthcare professional.

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

Your doctor or healthcare provider will give you the injection in the arm or buttock every two weeks. Next time the injection will be given into the other arm or buttock, and so on. **The injection is not to be given intravenously.**

If you forget your appointment to have RISPERDAL CONSTA

It is very important to keep all your appointments and get your medicine on time.

Contact your doctor as soon as you can if you think you are going to miss or have missed your appointment.

If you receive too much RISPERDAL CONSTA (Overdose)

As RISPERDAL CONSTA is given to you under the supervision of your doctor, it is very unlikely that you will receive too much.

However, if you experience any side effects after being given RISPERDAL CONSTA, you may need urgent medical attention.

You should immediately:

- phone the Poisons Information Centre (in Australia telephone **13 11 26** and in New Zealand telephone **0800 POISON** or **0800 764 766**), or
- contact your doctor, or
- go to the Emergency Department at your nearest hospital.

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

5. What should I know while using RISPERDAL CONSTA?

Things you should do

- **Follow your doctor's instructions carefully. Do not miss an injection or stop the treatment without consulting your doctor first.**
- **Be careful during strenuous exercise or exposure to extreme heat. Try to drink plenty of water.**
- **Avoid excessive eating.** There is a possibility of weight gain when using RISPERDAL CONSTA. Your doctor may monitor your body weight or recommend strategies to assist with weight management.
- If you are premenopausal, tell your doctor if you do not have a period for more than six months while using RISPERDAL CONSTA, even if you are not pregnant.

Call your doctor straight away if you:

- notice any involuntary movements of the tongue, mouth, cheeks or jaw which may progress to the arms and legs.

These may be symptoms of a condition called Tardive Dyskinesia, which can develop in people taking antipsychotic medicines, including RISPERDAL CONSTA. This condition is more likely to occur during longer treatment in older women. In very rare cases, these symptoms may be permanent. However, if detected early, these symptoms are usually reversible.

Remind any doctor, dentist or pharmacist you visit that you are using RISPERDAL CONSTA.

Things you should not do

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.

Driving or using machines

Be careful before you drive or use any machines or tools 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.

If the medicine makes you feel light-headed, dizzy or faint, be careful when getting up from a sitting or lying position. Getting up slowly may help.

Drinking alcohol

Do not drink alcohol.

RISPERDAL CONSTA can increase the effects of alcohol.

Looking after your medicine

RISPERDAL CONSTA will be stored by your doctor or pharmacist. The injection is kept in a refrigerator at 2°C to 8°C or where refrigeration is not available, in a cool dry place, protected from light, where the temperature stays below 25°C for no longer than 7 days.

6. Are there any side effects?

All medicines can have side effects. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention.

See the information below and, if you need to, ask your doctor or pharmacist if you have any further questions about side effects.

Less serious side effects

Less serious side effects	What to do
difficulty thinking, working or carrying out your usual daily activities because of: • headache • trembling, muscle weakness, unsteadiness on your feet, lack of coordination or slow, shuffling walk (symptoms of Parkinsonism) • drowsiness, sleeplessness or difficulty concentrating • nightmares • difficulty speaking • blurred vision • fainting • dizziness • swelling or pain at injection site • any problems with confusion or unsteadiness • pain in parts of your body, e.g. tooth ache, in the back, ear, mouth, throat, hands or feet muscle, joint, nerve or movement changes such as: • shaking or trembling • fatigue or weakness • restlessness in the legs or difficulty sitting still	Tell your doctor if you notice any of these less serious side effects and they worry you.

Less serious side effects	What to do
• uncontrolled muscle spasms, twitching, jerking or writhing movements • unusually reduced or slow body movement • a jerky feeling in your arm or leg that you can sense when rotating your limb or joint • muscle weakness, pain, spasms, twitching or stiffness • joint stiffness or pain • tingling or numbness of the hands or feet • decreased feeling of sensitivity, especially in your skin • difficulty in walking • involuntary changes in posture behavioural changes such as: • irritability or agitation • unusual anxiety or depression other changes such as: • cold or "flu-like symptoms, e.g. cough, blocked or runny nose, sneezing, sore throat • fever, chills, shortness of breath, cough, phlegm and occasionally blood (signs of pneumonia) • indigestion, stomach discomfort or pain, constipation or diarrhoea • nausea or vomiting • dry mouth or excessive thirst • excessive saliva or drooling • acne • dry skin • swelling of any part of your body, e.g. hands, ankles or feet • fever • unexplained weight gain or loss • inability to or feeling burning pain when passing urine • some loss of bladder control • breast abnormalities - breast discomfort or swelling or unusual secretion of breast milk • missed or irregular menstrual periods • sexual function disturbances - erectile dysfunction, problems with ejaculation, decreased sexual drive • unexplained decreased or increased appetite • dizziness on standing up, especially when getting up from a sitting or lying position	

Less serious side effects	What to do
- fast heart rate or chest discomfort - shortness of breath or wheezing - increased sensitivity to light - rash or itchy, red skin - an increase of CPK (creatine phosphokinase) in your blood, an enzyme which is sometimes released with muscle breakdown or changes in liver function results. These can only be detected by blood tests that your doctor may ask to be done.	

Serious side effects

Serious side effects	What to do
- rash, itching or hives on the skin; shortness of breath, wheezing or difficulty breathing; swelling of the face, lips, tongue or other parts of the body. If you have them, you may have had a serious allergic reaction to RISPERDAL CONSTA. Signs of heart or blood pressure problems including: - fainting, blurry vision, light-headedness or dizziness particularly on standing that persists despite sitting or lying down again - very fast heart rate, slowed heart rate, heart rhythm irregularities Signs of lung problems including: - sudden shortness of breath, trouble breathing, wheezing or gasping when you breathe, light-headedness or dizziness Signs of high blood sugar or diabetes such as: - unusual thirst, tiredness, upset stomach or need to urinate more often than usual body temperature changes such as: - fever - unexplained high body temperature, excessive sweating or rapid breathing	Tell your doctor immediately, or go to Accident and Emergency at your nearest hospital if you notice any of these serious side effects.

Serious side effects	What to do
- severe muscle stiffness or fits - involuntary movements of the tongue, face, mouth, jaw, arms, legs or trunk - severe or life-threatening rash with blisters and peeling skin that may start in and around the mouth, nose, eyes, and genitals and spread to other areas of the body (Stevens-Johnson syndrome or toxic epidermal necrolysis). - sudden weakness or numbness of the face, arms, or legs, especially on one side, or instances of slurred speech (these are called mini-strokes)	

Tell your doctor or pharmacist if you notice anything else that may be making you feel unwell.

Other side effects not listed here may occur in some people.

Reporting side effects

After you have received medical advice for any side effects you experience, you can report side effects to the Therapeutic Goods Administration online at www.tga.gov.au/reporting-problems. By reporting side effects, you can help provide more information on the safety of this medicine.

Always make sure you speak to your doctor or pharmacist before you decide to stop taking any of your medicines.

7. Product details

This medicine is only available with a doctor's prescription.

What RISPERDAL CONSTA contains

Active ingredient (main ingredient)	risperidone
Other ingredients (inactive ingredients)	Powder: - Polyglactin Diluent: - polysorbate 20 - carmellose sodium - dibasic sodium phosphate dihydrate - citric acid - sodium chloride - sodium hydroxide - water for injections

Do not take this medicine if you are allergic to any of these ingredients.

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

RISPERDAL CONSTA 25mg - AUST R 81489

RISPERDAL CONSTA 37.5mg - AUST R 81490

RISPERDAL CONSTA 50mg - AUST R 81491

Who distributes RISPERDAL CONSTA

Janssen-Cilag Pty Ltd

1-5 Khartoum Road Macquarie Park NSW 2113

Telephone: 1800 226 334

NZ Office: Auckland, New Zealand

Telephone: 0800 800 806

This leaflet was prepared in September 2025.

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