

RISPERDAL CONSTA®

INTRAMUSCULAR INJECTION

Risperidone

Consumer Medicine Information (CMI)

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 are given RISPERDAL CONSTA

When you must not be given it

You should not be given RISPERDAL CONSTA:

- if you know you are allergic to any of its ingredients (see the last section of this leaflet for a list of ingredients)
Signs of allergy include skin rash, itching, shortness of breath, and/or swollen face
- if the packaging is torn or shows signs of having been tampered with.

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:

- 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.
- unusual, excessive sweating or diarrhoea, dehydration or problems with your body temperature regulation
- kidney or liver problems
- you are prone to dizziness when standing up from lying or sitting position
- Parkinson's disease (a progressive movement and thinking disorder that tends to affect older people)
- dementia or Lewy body dementia
Older people suffering dementia may be at increased risk of stroke or death with RISPERDAL CONSTA.
- sugar diabetes
- unusual thirst, tiredness, blurred vision, upset stomach or need to urinate - common signs of high blood sugars
- epilepsy, seizures or fits
- continuous and/or painful erections (called 'priapism')
- involuntary movements or unusual restlessness or difficulty sitting still
- suicidal thoughts or past suicide attempts

- low blood potassium levels (hypokalaemia)
- breast cancer
- cancer of the pituitary gland
- 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)
- Tardive dyskinesia (a reaction to some medicines with uncontrollable twitching or jerking movements of the tongue, face, mouth, jaw, arms and legs)
- 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

- 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).

2. Tell your doctor if:

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

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 are pregnant or are planning to become pregnant**

Your doctor will advise you whether you should take RISPERDAL CONSTA

Newborn babies of mother taking RISPERDAL CONSTA in their last trimester may be at risk of having difficulty feeding or breathing, shaking, muscle

stiffness and/or weakness, sleepiness or agitation.

- **you are breast feeding**

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

- **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.

If you have not told your doctor or nurse about any of the above, tell them before you are given RISPERDAL CONSTA.

Taking other medicines

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

In particular, tell your doctor if you are taking:

- sleeping tablets, tranquillisers, strong painkillers, or some allergy medications called antihistamines and alcohol
- medicines that increase the activity of the central nervous system (psychostimulants such as methylphenidate).
- medicines used to treat bacterial infections such as rifampicin
- medicines used to treat fungal infections such as itraconazole and ketoconazole
- medicines to treat HIV/AIDS, such as ritonavir and tipranavir
- other medicines to treat mental illness or psychotic conditions
- medicines to treat depression, panic disorder, anxiety or obsessive-compulsive disorder, such as fluoxetine, paroxetine, sertraline and fluvoxamine
- medicines for your heart or blood pressure

- verapamil, a medicine used to treat high blood pressure and/or abnormal heart rhythm
- frusemide, a medicine used to treat high blood pressure and fluid build up
There is an increased risk of side effects or death in older people if frusemide is also taken with RISPERDAL CONSTA.
- medicines to treat epilepsy
- carbamazepine, a drug mainly used for epilepsy or trigeminal neuralgia (severe pain attacks in the face)
- medicines to treat Parkinson's disease or tremor.

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

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.

How it is given

RISPERDAL CONSTA will be given to you by injection by a healthcare professional. It 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 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. Injection is not to be given intravenously.

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.

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.

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.

What if you missed a dose

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.

Your doctor will decide what you should do next.

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, tell you doctor immediately or go to Accident and Emergency at your nearest hospital.

You may need urgent medical attention.

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. Do not miss an injection or stop the treatment without consulting your doctor first.

Your doctor will be happy to discuss any questions you may have with your treatment.

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.

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.

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.

Be careful during strenuous exercise or exposure to extreme heat. Try to drink plenty of water.

Do not drink alcohol.

RISPERDAL CONSTA can increase the effects of alcohol.

Things to be careful of

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, including herbal treatments and medicines that can be bought in a pharmacy or supermarket.

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. 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.

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.

Side Effects

All medicines can have side effects. Sometimes they are serious, but most of the time they are not. Your doctor has weighed the risks of using this medicine against the benefits they expect it will have for you.

All medicines can have side effects. You may need medical treatment if you get some of the side effects.

Ask your doctor or pharmacist to answer any questions you may have.

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

Tell your doctor if you notice any of the following and they worry you:

- 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
 - 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
 - signs of high blood sugar such as unusual thirst, tiredness or need to urinate more often than usual
 - 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
 - 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.

Tell your doctor immediately, or go to Accident and Emergency at your nearest hospital if you notice any of the following:

- 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
 - 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)

These are very serious side effects. You may need urgent medical attention or hospitalisation.

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

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

Do not be alarmed by this list of possible side effects.

You may not experience any of them.

After using RISPERDAL CONSTA

Storage

RISPERDAL CONSTA will be stored by your doctor or pharmacist. The injection is kept in a cool dry place, protected from light, where the temperature stays below 25°C.

Your doctor or pharmacist will not use it beyond the expiry date (month and year) printed on the pack.

Medicines cannot be stored indefinitely, even if stored properly.

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, sodium chloride, sodium hydroxide and water for injections.

Sponsor

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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

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