RISVAN®

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 RISVAN?

RISVAN contains the active ingredient risperidone which belongs to the group of medicines called "antipsychotics".

RISVAN is used to treat schizophrenia in adult patients.

For more information, see Section 1. Why am I using RISVAN? in the full CMI.

2. What should I know before I use RISVAN?

Do not use RISVAN 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, 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 RISVAN? in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with RISVAN 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 do I use RISVAN?

- The information for your doctor or nurse on the right way to reconstitute RISVAN is included in the package.
- Your doctor or healthcare provider will give you the injection with a single use device in the arm or buttock.
- Injection is not to be given intravenously.

More instructions can be found in Section 4. How do I use RISVAN? in the full CMI.

5. What should I know while using RISVAN?

Things you should do	• Remind any doctor, dentist or pharmacist you visit that you are using RISVAN.
Things you should not do	• Do not stop using this medicine suddenly
Driving or using machines	• Do not drive or use any tools or machines without talking to your doctor first. • Dizziness, tiredness, and vision problems may occur during treatment with RISVAN.
Drinking alcohol	• You should avoid drinking alcohol when using RISVAN.
Looking after your medicine	• Do not store above 25°C. Store in the original package in order to protect from moisture. • Use RISVAN immediately after reconstitution.

For more information, see Section 5. What should I know while using RISVAN? in the full CMI.

6. Are there any side effects?

The most serious side effects that may occur are tardive dyskinesia (twitching or jerking movements that you cannot control in your face, tongue, or other parts of your body); blood clots in the veins, especially in the legs (symptoms include swelling, pain and redness in the leg); fever, muscle stiffness, sweating or a lowered level of consciousness; prolonged or painful erection; severe allergic reaction characterized by fever, swollen mouth, face, lip or tongue, shortness of breath, itching, skin rash or drop in blood pressure (anaphylactic reaction or angioedema); dark red or brown urine or notable decreased urination with muscle weakness or trouble moving arms and legs (signs of rhabdomyolysis); weakness or lightheadedness, fever, chills, or sores in the mouth. The most common side effects are difficulty falling or staying asleep; movement disorders that may include slow or impaired movements, sensation of stiffness or tightness of the muscles, a slow shuffling walk, tremor while at rest, increased saliva and/or drooling, and a loss of expression on the face (signs of Parkinsonism); headache.
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.

RISVAN®

Active ingredient(s): *risperidone*

Consumer Medicine Information (CMI)

This leaflet provides important information about using RISVAN. **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 RISVAN.**

Where to find information in this leaflet:

1. Why am I using RISVAN?
2. What should I know before I use RISVAN?
3. What if I am taking other medicines?
4. How do I use RISVAN?
5. What should I know while using RISVAN?
6. Are there any side effects?
7. Product details

1. Why am I using RISVAN?

RISVAN contains the active ingredient risperidone which belongs to the group of medicines called 'antipsychotics'.

RISVAN is used in adult patients to treat schizophrenia, where you may see, hear or feel things that are not there, believe things that are not true or feel unusually suspicious, or confused.

RISVAN is intended for patients who show tolerability and effectiveness to oral (e.g., tablets) risperidone.

RISVAN can help alleviate the symptoms of your condition and stop your symptoms from coming back.

2. What should I know before I use RISVAN?

Warnings

Do not use RISVAN if:

- You are allergic (hypersensitive) to risperidone, or any of the other ingredients of this medicine 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:

- Are prone to dizziness when standing up or lying from sitting position.
- Have a heart problem. Examples include an irregular heart rhythm or if you are using medicines for your high blood pressure. RISVAN may cause low blood pressure. Your dose may need to be adjusted.
- Know of any factors which would favour you having a stroke, such as high blood pressure, cardiovascular disorder or blood vessel problems in the brain.
- Have ever experienced involuntary movements of the tongue, mouth and face.
- Have ever had a condition whose symptoms include high temperature, muscle stiffness, sweating or a lowered level of consciousness (also known as Neuroleptic Malignant Syndrome).
- Have Parkinson's disease.
- Have dementia.
- 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).
- Are diabetic.
- Have epilepsy.
- Are a man and you have ever had a prolonged or painful erection.
- Have problems controlling your body temperature or overheating.
- Have kidney problems.
- Have liver problems.
- Have an abnormally high level of the hormone; prolactin in your blood or if you have a tumour, which is possibly dependent on prolactin.
- Or someone else in your family has a history of blood clots, as antipsychotics have been associated with formation of blood clots.

Dangerously low numbers of a certain type of white blood cell needed to fight infection in your blood has been seen very rarely with patients taking risperidone. Your doctor may therefore check your white blood cell counts before and during treatment.

Even if you have previously tolerated oral risperidone, rarely allergic reactions occur after receiving injections of RISVAN. Seek medical attention right away if you experience a rash, swelling of your throat, itching, or breathing problems as these may be signs of a serious allergic reaction.

RISVAN may cause you to gain weight. Significant weight gain may adversely affect your health. Your doctor should regularly measure your body weight.

Diabetes mellitus or worsening of pre-existing diabetes mellitus have been seen with patients taking RISVAN. Your doctor should therefore check for signs of high blood sugar. In patients with pre-existing diabetes mellitus blood glucose should be monitored regularly.

RISVAN commonly raises levels of a hormone called "prolactin". This may cause side effects such as menstrual disorders or fertility problems in women, breast swelling in men (see section 6: Are there any side effects?). If such side effects occur, evaluation of the prolactin level in the blood is recommended.

During an operation on the eye for cloudiness of the lens (cataract), problems may arise 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.

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

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine. Your doctor will decide if you can use it.

The following symptoms may occur in newborn babies, of mothers that have used risperidone in the last trimester (last three months of their pregnancy): shaking, muscle stiffness, and/or weakness, sleepiness, agitation, breathing problems, and difficulty in feeding. If your baby develops any of these symptoms, you may need to contact your doctor.

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

RISVAN can raise your levels of a hormone called "prolactin" that may impact fertility (see section 6: Are there any side effects?).

Elderly

- RISVAN should be used with caution in elderly. RISVAN is NOT indicated in elderly people with dementia.

Children and adolescents

- Do not give this medicine to children and adolescents under 18 years old.

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 RISVAN and affect how it works.

It is especially important to talk to your doctor or pharmacist if you are taking any of the following:

- Medicines that work on your brain such as to help you calm down (benzodiazepines) or some medicines for pain (opiates), medicines for allergy (some antihistamines), as RISVAN may increase the sedative effect of all of these.
- Medicines that may change the electrical activity of your heart, such as medicines for malaria, heart rhythm problems, allergies (antihistamines), some antidepressants or other medicines for mental problems.
- Medicines that cause a slow heartbeat.
- Medicines that cause low blood potassium (such as certain diuretics).
- Medicines to treat raised blood pressure. RISVAN can lower blood pressure
- Medicines for Parkinson's disease (such as levodopa).
- Medicines that increase the activity of the central nervous system (psychostimulants, such as methylphenidate).
- Medicines used for heart problems or swelling of parts of your body due to accumulation of too much fluid - water tablets (diuretics, such as furosemide or chlorothiazide). RISVAN taken by itself or with furosemide, may have an increased risk of stroke or death in elderly people with dementia.

Medicines that may <u>increase</u> the effect of RISVAN include:

- Medicines used to treat certain types of heart disease (quinidine, disopyramide, procainamide, propafenone, amiodarone, sotalol).
- Medicines used to treat depression and other psychiatric disorders (paroxetine, sertraline fluoxetine, fluvoxamine and tricyclic antidepressants)
- Medicines used to treat high blood pressure (beta-blockers).
- Medicines used to treat psychosis or to calm down (phenothiazines).
- Medicine blockers used to treat of the acidity of stomach (cimetidine, ranitidine).
- Medicines used to treat fungal infections (itraconazole and ketoconazole).
- Certain medicines used to treat HIV/AIDS, such as ritonavir.

If you start or stop taking such medicines, you may need a different dose of risperidone.

Medicines that may <u>reduce</u> the effect of RISVAN include:

- Medicine for treating some infections (rifampicin)
- Medicines used to treat epilepsy {carbamazepine, phenytoin, phenobarbital)

If you start or stop taking such medicines, you may need a different dose of risperidone.

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

4. How do I use RISVAN?

How much to use

- RISVAN 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.
- You will be given RISVAN as an intramuscular injection either in the upper arm or buttock every 28 days, by a healthcare professional. Injections should be alternated between the right and left sides.

Healthcare professionals should click on the link for the instructions on how to inject RISVAN 75 mg and RISVAN 100 mg.
https://medsinfo.com.au/media/seirisva

Please look for the QR code on the medicine pack. Scan this code with your smart phone for more information on RISVAN.

When to use RISVAN

- The recommended dose is 75 mg every 28 days, but a higher dose of 100 mg every 28 days may be necessary. Your doctor will decide on the dose of RISVAN that is right for you.

How to use RISVAN powder and diluent for prolonged-release suspension for injection

- If you are currently treated with other antipsychotics than risperidone, but have taken risperidone in the past, you should begin taking oral risperidone with at least 6 days before beginning treatment with RISVAN.
- If you have never taken any form of risperidone, you should begin taking oral risperidone with at least 14 days before beginning treatment with RISVAN. The duration of the oral risperidone period will be determined by your physician.

People with kidney problems

RISVAN is not recommended in patients with moderate to severe impaired kidney function.

If you forget to use RISVAN

If you think that you did not receive a dose, you should contact your doctor or another healthcare provider immediately.

If you use too much RISVAN

If you think that you have used too much RISVAN, you may need urgent medical attention.

You should immediately:

- phone the Poisons Information Centre (**by calling 13 11 26**), or
- contact your doctor, or
- go to the Emergency Department at your nearest hospital.

You should do this even if there are no signs of discomfort or poisoning.

5. What should I know while using RISVAN?

Things you should do

It is important not to miss your appointments when you are supposed to receive your injections of this medicine once every 28 days. If you cannot keep your appointment, make sure to contact your doctor right away to discuss another date when you can come in for your injection.

Call your doctor straight away if you:

- If you think that the symptoms of your disease condition are coming back.

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

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

Things you should not do

- Do not stop using this medicine suddenly [if relevant].
- If you stop using RISVAN, you will lose the effects of the medicine. You should not stop using this medicine unless told to do so by your doctor as your symptoms may return.

Driving or using machines

Do not drive or use any tools or machines without talking to your doctor first.

Dizziness, tiredness, and vision problems may occur during treatment with RISVAN.

Drinking alcohol

You should avoid drinking alcohol when using RISVAN.

Alcohol may worsen the symptoms of your condition.

Looking after your medicine

- RISVAN will be stored by your doctor or pharmacist. The injection is to be kept in the original package and in a cool dry place, 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.
- RISVAN will be given to you by your doctor immediately after reconstitution.

Keep it where young children cannot reach it.

Getting rid of any unwanted medicine

If you no longer need to use this medicine or it is out of date, take it to any pharmacy for safe disposal.

Do not use this medicine after the expiry date.

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.

Serious side effects

Serious side effects	What to do
Head and neurology related: • Tardive Dyskinesia - experiencing involuntary rhythmic movements, twitching or jerking movements that you cannot control in your face, tongue, or other parts of your body. • Experience fever, muscle stiffness, sweating or a lowered level of consciousness (a	**Immediately visit the Emergency Department at your nearest hospital if you notice any of these serious side effects.**

Serious side effects	What to do
disorder called "Neuroleptic Malignant Syndrome"). • Dizziness • Tremor (shaking) • Brain ischemia (insufficient blood flow to the brain) • Unresponsive to stimuli, loss of consciousness, low level of consciousness • Convulsion (fits), fainting • Blood vessel problems in the brain • Coma due to uncontrolled diabetes **Blood clots related:** • 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. **Reproductive system related:** • If you are a man and experience prolonged or painful erection. This is called priapism. **Allergy related:** • Experience severe allergic reaction characterized by fever, swollen mouth, face, lip or tongue, shortness of breath, itching, skin rash or drop in blood pressure (anaphylactic reaction or angioedema). You may experience severe allergic reactions to RISVAN even if you were not allergic to risperidone tablets. **Muscles and joints related:** • You have a dark red or brown urine or notable decreased urination along with muscle weakness or trouble moving arms and legs. These may be signs of rhabdomyolysis (a rapid damage of your muscles). **Blood related:** • You have weakness or lightheadedness, fever, chills, or sores in the mouth. These may be signs of very low number of granulocytes (a type of white blood cell to help you against infection).	

Less Serious Side Effects

Other side effects	What to do
Mental system related: • Difficulty falling or staying asleep. • Sleep disorder • Irritability • Depression • Anxiety • Feeling sleepy, or less alert • Mania (elated mood) • Confusion • Decreased sexual drive Nervousness • Nightmares. • Sleep walking. • Sleep-related eating disorder. • Lack of emotion, inability to reach orgasm. **Head and neurology related:** • Parkinsonism: movement disorders that slow or impaired movements, sensation of stiffness or tightness of the muscles, and sometimes even a sensation of movement "freezing up" and then restarting. Other signs include a slow shuffling walk, a tremor while at rest, increased saliva and/or drooling, and a loss of expression on the face. • Headache. • Dystonia, which is slow or sustained involuntary contraction of muscles which can involve any part of the body and may result in abnormal posture • Dyskinesia, which can be repetitive, spastic, writhing movements, or twitching movements of the involuntary muscles • Akathisia, which is inability to stay still. • A restless urge to move parts of your body, balance disorder, abnormal coordination, dizziness upon standing, poor 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 on the skin. • Involuntary shaking of the head.	**Contact your doctor if you experience any of the side effects listed in this table.**

Other side effects	What to do
Infections related: • Pneumonia (lung infection), bronchitis (infection of the main airways of the lungs), sinus infection, urinary tract infection, ear infection, flu, flu-like symptoms, sore throat, cough, stuffy nose, fever, eye infection or "pink eye" • Bladder infection, tonsillitis, fungal infection of nails, infection of the deeper layers of skin, viral infection, inflammation of the skin caused by mites. **Blood related:** • Decrease or increase in white blood cells in your blood • Decrease in platelets (blood cells that help you stop bleeding) • Anemia or decrease in red blood cells • Increase in blood creatine phosphokinase enzyme • Increased liver enzymes which can cause changes in liver function tests that your doctor may ask to be done. **Allergy related:** • Allergic reaction. **Hormones and metabolism related:** • Raised levels of a hormone called "prolactin" found in a blood test. Symptoms of high prolactin occur uncommonly and may include in men breast swelling, difficulty in getting or maintaining erections, decreased sexual desire. • Weight gain, increased or decreased appetite. • Inappropriate secretion of a hormone that controls urine volume. • Excess of sugar in the urine, low blood sugar. • Dangerously excessive intake of water. • Increased insulin (a hormone that controls blood sugar levels) in your blood. **Eye related:** • Blurry vision. • Oversensitivity of the eyes to light, dry eye, increased tears, redness of the eyes.	

Other side effects	What to do
• Glaucoma (increased pressure within the eye), problems with movement of your eyes, eye rolling, eyelid margin crusting/inflammation. • Eye problems during cataract surgery. **Ear related:** • Sensation of spinning (vertigo), ringing in the ears, ear pain. **Heart and blood vessels related:** • Irregular and often rapid heart rate, slow heart rate, abnormal electrocardiogram (test that measures the electrical activity of the heartbeat), palpitations (a fluttering or pounding feeling in your chest) • Low blood pressure, drop in blood pressure after standing, flushing. **Lung related:** • Congestion of breathing passages, wheezing (coarse/whistling sound during breathing), nose bleeds. • Trouble breathing during sleep (sleep apnea), fast, shallow breathing. • Lung infection caused by inhaling food into the breathing passages, lung congestion, breathing passage disorder, voice disorder, crackly lung sounds. **Gastrointestinal related:** • Abdominal pain, abdominal discomfort, vomiting, nausea, constipation, diarrhea, indigestion, dry mouth, toothache. • Stomach or intestinal infection or irritation, fecal incontinence, difficulty swallowing, excessive passing of gas or wind. • Inflammation of the pancreas, a blockage in the bowels. • Swollen tongue, chapped lips. • Lack of bowel muscle movement that causes blockage. **Liver related:** • Jaundice (yellowing of the skin and the eyes). **Skin related:** • Rash, skin redness.	

Other side effects	What to do
• Hives, thickening of skin, skin disorder, intense itching of the skin, hair loss, eczema (patches of skin become inflamed, itchy, cracked, and rough), dry skin, skin discoloration, acne, seborrheic dermatitis (red, scaly, greasy, itchy, and inflamed skin), skin lesion. • Dandruff. • Hardening of the skin **Muscles and joints related:** • Muscle spasms, bone or muscle pain, back pain, joint pain. • Abnormal posture, joint stiffness, joint swelling, muscle weakness, neck pain, walking abnormality, thirst, feeling unwell, chest discomfort or general discomfort, feeling "out of sorts". **Urinary related:** • Incontinence (involuntary leakage of urine). • Frequent passing of urine, inability to pass urine, pain when passing urine. **Reproductive system related:** • Erectile dysfunction, ejaculation disorder, development of breast in men. • Loss of menstrual periods or other problems with your cycle (females). • Lack of ovulation • Fertility problems • Leakage of milk from the breasts, sexual dysfunction, breast pain or discomfort, vaginal discharge. • Breast enlargement, breast engorgement (hard, swollen, painful breasts from too much breast milk production). **General disorders related:** • Swelling of the body, arms or legs, chest pain, lack of energy and strength, fatigue, pain. • Chills. • Feeling thirsty, feeling unwell, chest discomfort, feeling "out of sorts", general discomfort • Decreased body temperature, coldness in arms and legs. • Symptoms of drug withdrawal (also in newborns).	

Other side effects	What to do
Injection site related: • A reaction at the injection site, including discomfort, pain, redness or swelling. • Fall. • Procedural pain.	

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 RISVAN contains

Active ingredient (main ingredient)	risperidone
Other ingredients (inactive ingredients)	Pre-filled syringe of powder: polyglactin. Pre-filled syringe of diluent: dimethyl sulfone

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

What RISVAN looks like

Each kit box of RISVAN powder and diluent for prolonged-release suspension for injection contains:

- An aluminium pouch with one pre-filled syringe containing powder (within this powder is the active ingredient, risperidone) and a silica gel desiccant sachet. The powder is white to white-yellowish, non-aggregated.
- An aluminium pouch with one pre-filled syringe containing the diluent and a silica gel desiccant sachet. The pre-filled syringe of the diluent contains a clear solution and has a red (RISVAN 75 mg, AUST R 377801) or a blue (RISVAN 100 mg, AUST R 388583) finger flange.
- One sterile needle for IM injection 2 inch (0.90 x 51mm [20G]) with safety shield used for gluteus administration.

- One sterile needle for IM injection 1 inch (0.80 x 25mm [21G]) with safety shield used for deltoid administration.

RISVAN is registered on the Australian Register of Therapeutic Goods. Australian Register Numbers:

RISVAN 75 mg: AUST R 377801

RISVAN 100 mg: AUST R 388583

Who distributes RISVAN

Servier Laboratories (Aust.) Pty. Ltd.

www.servier.com.au

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