

# Risperidone Lupin

## 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 Risperidone Lupin?

Risperidone Lupin contains the active ingredient risperidone. Risperidone Lupin is used to improve the symptoms of certain types of mental illness.

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

### 2. What should I know before I use Risperidone Lupin?

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, 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 Risperidone Lupin?](#) in the full CMI.

### 3. What if I am taking other medicines?

Some medicines may interfere with Risperidone Lupin 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 Risperidone Lupin?

- Your doctor will decide the dose suitable for you based on your condition and response.

More instructions can be found in Section [4. How do I use Risperidone Lupin?](#) in the full CMI.

### 5. What should I know while using Risperidone Lupin?

<b>Things you should do</b>	<ul style="list-style-type: none"><li>Remind any doctor, dentist, or pharmacist you visit that you are using Risperidone Lupin.</li><li>If you are pre-menopausal, tell your doctor if you do not have a period for more than six months while using this medicine, even if you are not pregnant.</li></ul>
<b>Things you should not do</b>	<ul style="list-style-type: none"><li>Do not give this medicine to anyone else, even if they have same condition as you.</li><li>Do not use this medicine, if the appearance of oral solution has changed.</li></ul>
<b>Driving or using machines</b>	<ul style="list-style-type: none"><li>Risperidone Lupin may cause dizziness or light-headedness in some people, especially after the first dose. Make sure you know how you react to Risperidone Lupin before you drive a car, operate machinery, or do anything else that could be dangerous if you are dizzy.</li></ul>
<b>Drinking alcohol</b>	<ul style="list-style-type: none"><li>Risperidone Lupin may increase the effects of alcohol.</li><li>Do not drink alcohol.</li></ul>
<b>Looking after your medicine</b>	<ul style="list-style-type: none"><li>Keep Risperidone Lupin below 30°C.</li><li>Do not refrigerate.</li></ul>

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

### 6. Are there any side effects?

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.

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

# Risperidone Lupin

Active ingredient: *risperidone*

## Consumer Medicine Information (CMI)

This leaflet provides important information about using Risperidone Lupin. **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 Risperidone Lupin.**

Where to find information in this leaflet:

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

## 1. Why am I using Risperidone Lupin?

**Risperidone Lupin contains the active ingredient risperidone.** Risperidone Lupin belongs to a group of medicines called antipsychotic agents which improve the symptoms of certain types of mental illness

**Risperidone Lupin is used for:**

- treatment of sudden (acute) and long-term (chronic) schizophrenia and other types of related psychoses. These are disorders related to thought, feeling and/or action.
- short-term treatment of acute mania associated with bipolar 1 disorder. This condition is characterised by symptoms such as elevated, expansive or irritable mood, inflated self-esteem, decreased need for sleep, pressured speech, racing thoughts, distractibility or poor judgement including disruptive or aggressive behaviours.
- treatment of behavioural problems in patients with a decline in mental ability (dementia) caused by Alzheimer's disease. These problems include: aggression through words or action, morbid suspiciousness, agitation or wandering.
- treatment of conduct and other disruptive behaviours such as aggression, impulsiveness and self-injury in children (over 5 years old), adolescents and adults who are intellectually disabled.
- treatment of behavioural symptoms of autism in children and adolescent.

Risperidone Lupin helps to correct a chemical imbalance in the brain associated with these conditions.

This medicine has been approved for the uses mentioned above. However, your doctor may prescribe it for another use. It is only available with a doctor's prescription.

**If you want more information, ask your doctor.**

Risperidone Lupin is not addictive.

## 2. What should I know before I use Risperidone Lupin?

### Warnings

**Do not use Risperidone Lupin if:**

- you are allergic to risperidone, or any of the ingredients listed at the end of this leaflet. Signs of allergy include skin rash, itching, shortness of breath, and/or swollen face.
- Always check the ingredients to make sure you can use this medicine.
- the packaging is torn or shows signs of being tampered with.
- the oral solution does not look right.

**Check with your doctor if you:**

- have or have ever had any other 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.
  - 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 Risperidone Lupin.
  - 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.
  - Tardive dyskinesia (a reaction to some medicines with uncontrollable twitching or jerking movements of the tongue, face, mouth, jaw, arms, and legs).
  - 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).
- 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 Risperidone Lupin. 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 Risperidone Lupin.
- have any eye surgery planned. Your doctor may recommend you stop treatment temporarily prior to your eye surgery.
- you will be in a hot environment or do a lot of vigorous exercise. Risperidone Lupin may make you sweat less, causing your body to overheat.

### **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 Risperidone Lupin.

Newborn babies of mothers taking Risperidone Lupin in their last trimester may be at risk of having difficulty feeding or breathing, shaking, muscle stiffness and/or weakness, sleepiness, or agitation.

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

As Risperidone Lupin is excreted in breast milk, it is recommended that you do not breastfeed while taking the medicine.

### **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.

In particular, tell your doctor if you are taking:

- Medicines that act on nervous system:
  - sleeping tablets
  - tranquillisers
  - strong pain-killers
  - psycho-stimulants, such as methylphenidate
  - certain antidepressants
  - alcohol
  - 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 a tremor
- Medicines acting on immune system:

- certain anti-allergy medicines called anti histamines;
- medicines to treat HIV/AIDS, such as ritonavir and tipranavir
- Anti-bacterial agents:
  - medicines such as rifampicin used to treat bacterial infections.
- Anti-fungal agents:
  - medicines such as itraconazole and ketoconazole to treat fungal infections.
- Anti-psychiatric medicines:
  - medicines to treat depression, panic disorder, anxiety or obsessive-compulsive disorder, such as fluoxetine, paroxetine, sertraline and fluvoxamine.
- Medicines to treat cardiovascular disorders:
  - 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 Risperidone Lupin.

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

### **4. How do I use Risperidone Lupin?**

#### **How much to take**

- It is very important that you take the correct amount of Risperidone Lupin, but this will vary from person to person.
- Your doctor will decide the dose suitable for you based on your condition and response
- Follow your doctor's instructions carefully and do not change or stop the required dosage without consulting your doctor first.
- Important note: never take more solution than your doctor tells you to take.

Your doctor will advise you on how much Risperidone Lupin you need.

#### **When to take Risperidone Lupin**

Risperidone Lupin may be taken as a single dose, once a day or in divided doses twice a day (in the morning and in the evening).

You may take Risperidone Lupin either with or between meals.

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.

## How to use Risperidone Lupin

Mix Risperidone Lupin oral solution with a non-alcoholic drink. Mineral water, orange juice, coffee and milk are suitable. Do not use tea.

### Directions for opening the bottle and using the pipette for Risperidone Oral Solution

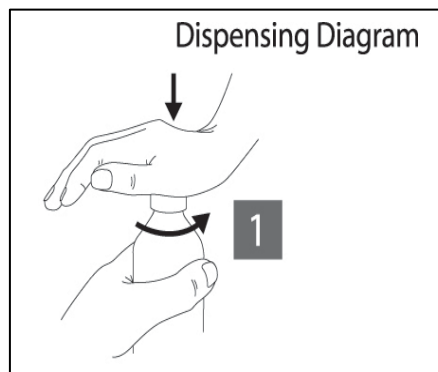
Always take this medicine exactly as your doctor has told you. Check with your doctor if you are not sure.

The solution comes with a syringe (pipette). Use only the syringe (pipette) delivered with this medicine for measuring the dose prescribed by your doctor.

**Figure 1:**

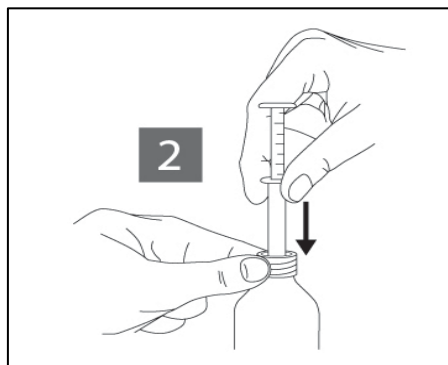
The bottle comes with a child-resistant cap, and should be opened as follows:

- To open, push the screw cap down while turning it anti-clockwise.
- Remove the unscrewed cap.



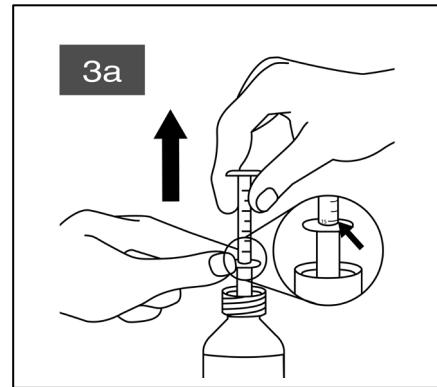
**Figure 2:**

Insert the pipette into the bottle.



**Figure 3 :**

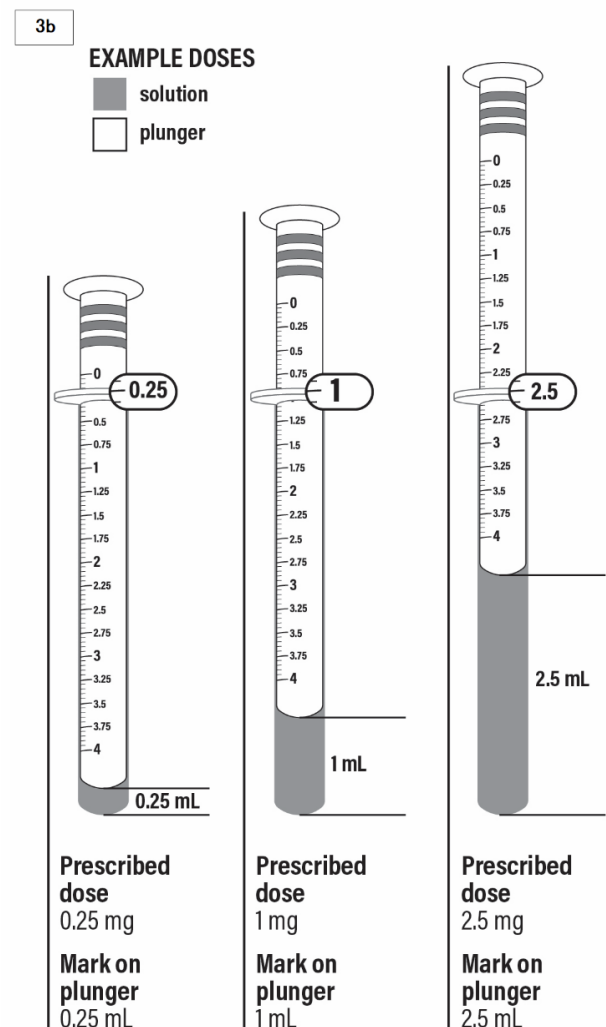
While holding the bottom ring (Figure 3a), pull the top ring up to the mark that corresponds to the number of millilitres or milligrams you need to give (See examples Figure 3b).



Measure the exact dose of medicine you need. Pay attention when measuring a small dose, for example for 0.25 mg, measure 0.25 mL (a quarter millilitre); for 0.5 mg, measure 0.5 mL (half a millilitre).

1 mL of RISPERDAL oral solution contains 1 mg risperidone. The measured volume is printed every 0.25 mL / 0.25 mg on the plunger.

Figure 3b shows examples of prescribed doses and corresponding marks on the plunger.

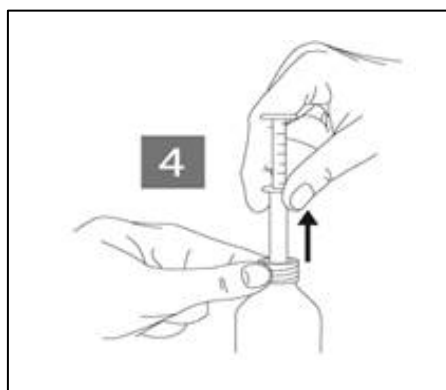


**Figure 4:**

Holding the bottom ring, remove the entire pipette from the bottle.

Empty the contents of the pipette into a non-alcoholic drink by sliding the upper ring down. Mineral water, orange juice, coffee and milk are suitable. Do not use tea.

Close the bottle. Rinse the pipette with some cold water after use, let it air dry and store it in its case. Use of detergents or extensive rubbing with a cloth may increase the risk of fading or disappearing print.



### **If you forget to use Risperidone Lupin**

Risperidone Lupin should be used regularly at the same time each day.

If you miss your dose at the usual time, take the missed dose as soon as you remember instead of your next dose. Then go back to taking it as you would normally.

**If it is almost time for your next dose, skip the dose you missed and take your next dose when you are meant to.**

**Do not take a double dose to make up for the dose you missed.**

If you forget to take Risperidone Lupin for a number of days or more, tell your doctor before starting your medicine again.

If you have problems remembering when to take your medicine, ask your pharmacist for some hints.

### **If you use too much Risperidone Lupin**

If you think that you have used too much Risperidone Lupin, 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.**

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 Risperidone Lupin?**

### **Things you should do**

- Always follow your doctor's instructions carefully and seek your doctor's advice before changing or stopping treatment.
- Continue taking the solution for as long as your doctor tells you. Risperidone Lupin helps control your condition but does not cure it. Therefore, you must take Risperidone Lupin every day.
- If you are pre-menopausal, tell your doctor if you do not have a period for more than six months while using Risperidone Lupin, even if you are not pregnant.
- Be careful during strenuous exercise or exposure to extreme heat. Try to drink plenty of water.
- Be careful when getting up from a sitting or lying position. If the medicine makes you feel light-headed, dizzy, or faint. Getting up slowly may help.
- Avoid excessive eating.

There is a possibility of weight gain when taking Risperidone Lupin. Your doctor may monitor your body weight or recommend strategies to assist with weight management.

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

### **Things you should not do**

- Do not give this medicine to anyone else, even if they have the same condition as you.
- Do not take this medicine to treat any other complaints unless your doctor or pharmacist tells you to.
- Do not stop taking it unless your doctor tells you to even if you feel better.
- Do not use Risperidone Lupin after the expiry date ("EXP") printed on the pack, even if it has been stored properly. Medicines cannot be stored indefinitely.
- Do not use Risperidone Lupin if the appearance of the oral solution has changed.

### **Driving or using machines**

**Be careful before you drive or use any machines or tools until you know how Risperidone Lupin affects you.**

Risperidone Lupin may cause dizziness or light-headedness in some people, especially after the first dose. Make sure you know how you react to Risperidone Lupin before you drive a car, operate machinery, or do anything else that could be dangerous if you are dizzy.

### **Drinking alcohol**

**Do not drink alcohol while taking Risperidone Lupin.**

Risperidone Lupin may increase the effects of alcohol.

### Looking after your medicine

- Keep Risperidone Lupin below 30°C. The oral solution should not be refrigerated.

Follow the instructions on the packaging on how to take care of your medicine properly.

Store it in a cool dry place away from moisture, heat, or sunlight; for example, do not store it:

- in the bathroom or near a sink; or
- in the car or on window-sills.

**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.

### Less serious side effects

Less serious side effects	What to do
<ul style="list-style-type: none"> <li>• <b>Mental function related:</b> <ul style="list-style-type: none"> <li>○ difficulty thinking, working, or carrying out your usual daily activities</li> <li>○ difficulty in concentrating</li> <li>○ confusion or unsteadiness.</li> </ul> </li> <li>• <b>Sleep related:</b> <ul style="list-style-type: none"> <li>○ excessive sleeping during the day</li> <li>○ sleeplessness</li> <li>○ drowsiness.</li> </ul> </li> <li>• <b>Nerve related:</b> <ul style="list-style-type: none"> <li>○ difficulty speaking</li> <li>○ trembling, unsteadiness on your feet, lack of co-ordination or slow, shuffling walk (symptoms of Parkinsonism)</li> <li>○ blurred vision</li> <li>○ fainting</li> <li>○ dizziness.</li> </ul> </li> <li>• <b>Pain related:</b> <ul style="list-style-type: none"> <li>○ headache</li> </ul> </li> </ul>	<p><b>Speak to your doctor if you have any of these less serious side effects and they worry you.</b></p>

Less serious side effects	What to do
<ul style="list-style-type: none"> <li>○ pains in parts of your body, eg. in the neck, back, ear, hands, or feet</li> <li>○ joint swelling or pain.</li> <li>• <b>Muscle, joint, nerve or movement changes such as:</b> <ul style="list-style-type: none"> <li>○ muscle weakness</li> <li>○ shaking or trembling</li> <li>○ muscle stiffness</li> <li>○ restlessness in the legs or difficulty sitting still</li> <li>○ uncontrolled muscle spasms, twitching, jerky or writhing movements</li> <li>○ muscle aches or pain</li> <li>○ walking abnormally or with difficulty</li> <li>○ abnormal posture, such as rigid body movements and persistent abnormal positions of the body.</li> </ul> </li> <li>• <b>Behavioural changes such as:</b> <ul style="list-style-type: none"> <li>○ irritability or agitation</li> <li>○ unusual anxiety or nervousness.</li> </ul> </li> <li>• <b>Digestive track related:</b> <ul style="list-style-type: none"> <li>○ indigestion</li> <li>○ stomach discomfort or pain</li> <li>○ diarrhoea</li> <li>○ constipation</li> <li>○ unexplained increase or decrease in appetite</li> <li>○ nausea or vomiting.</li> </ul> </li> <li>• <b>Skin related:</b> <ul style="list-style-type: none"> <li>○ dry skin</li> <li>○ rash, red skin or itchy skin</li> <li>○ thickening of the skin resulting in warts, corns, calluses</li> <li>○ skin infection</li> <li>○ swelling of any part of your body, eg. hands, ankles, or feet</li> <li>○ acne.</li> </ul> </li> <li>• <b>Respiratory function related:</b> <ul style="list-style-type: none"> <li>○ shortness of breath</li> <li>○ chest pain or discomfort</li> <li>○ cold or “flu-like” symptoms, eg. cough, blocked or runny nose, sneezing, sore throat</li> <li>○ feeling of tension or fullness in the nose, cheeks and behind your eyes, sometimes with a throbbing ache, fever, stuffy nose, and loss of the sense of smell (signs of sinusitis)</li> <li>○ cough</li> </ul> </li> </ul>	<p><b>Speak to your doctor if you have any of these less serious side effects and they worry you.</b></p>



## 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](http://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 Risperidone Lupin contains

<b>Active ingredient (main ingredient)</b>	Risperidone
<b>Other ingredients (inactive ingredients)</b>	Tartaric acid Benzoic acid Hydrochloric acid Purified water
<b>Potential allergens</b>	Benzoate

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

### What Risperidone Lupin looks like

Risperidone Lupin oral solution 1 mg/mL is a clear, colourless oral solution (AUST R 389690).

### Who distributes Risperidone Lupin

Generic Health Pty Ltd  
Suite 2, Level 2  
19-23 Prospect Street  
Box Hill, VIC, 3128

✉ [ghinfo@generichealth.com.au](mailto:ghinfo@generichealth.com.au)

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💻 [www.generichealth.com.au](http://www.generichealth.com.au)

This leaflet was prepared in July 2025.