

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 Rivotril®?

Rivotril® contains the active ingredient clonazepam. Rivotril® is used to treat epilepsy in infants, children and adults and it is also used to treat status epilepticus (prolonged or repeated fits or seizures without any recovery between attacks).

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

2. What should I know before I use Rivotril®?

Do not use if you have ever had an allergic reaction to clonazepam, other benzodiazepine medicines or any of the ingredients listed at the end of the CMI.

Do not use if you have severe and chronic lung disease or severe liver disease.

Do not use if you have an addiction to drugs or alcohol. This medicine may be addictive.

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 Rivotril®?](#) in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with Rivotril® 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 Rivotril®?

- Take Rivotril® exactly as your doctor has prescribed.
- Measure the prescribed dose of Rivotril® oral liquid as DROPS ONLY.

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

5. What should I know while using Rivotril®?

Things you should do	<ul style="list-style-type: none">• Remind any doctor, dentist or pharmacist you visit that you are using Rivotril®.• Do not take any other medicines whether they require a prescription or not without first telling your doctor.• Tell your doctor if you become pregnant while taking Rivotril®.• Tell your doctor if, for any reason, you have not taken your medicine exactly as prescribed.
Things you should not do	<ul style="list-style-type: none">• Do not stop using or lower the dose of this medicine suddenly.• Do not take Rivotril® for a longer time than your doctor has prescribed.• Do not take Rivotril® while taking sedatives, tranquilizers or hypnotics.
Driving or using machines	<ul style="list-style-type: none">• Do not drive or use any machines or tools until you know how Rivotril® affects you.
Drinking alcohol	<ul style="list-style-type: none">• You should not drink alcohol while taking Rivotril®. Alcohol may increase the effects of Rivotril® and lead to serious side effects.
Looking after your medicine	<ul style="list-style-type: none">• Keep the tablets in the blister foil in a cool dry place below 30°C.• Keep the oral liquid bottle in a cool dry place below 25°C.

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

6. Are there any side effects?

Mild side effects: drowsiness, tiredness, dizziness, unsteadiness, muscle weakness, tremor, loss of memory, inattentiveness, confusion, lack of concentration, headache, hangover feeling in the morning, slurred speech, unpleasant dreams, palpitations, vomiting, increased saliva in infants and children, chest congestion, double vision. **Serious side effects:** difficulties in breathing, chest pains, more fits than usual, sudden anxiety or excitation, hallucinations or delusions, depression or thoughts of self-harm, severe sleep disturbances, severe withdrawal symptoms following discontinuation of Rivotril®.

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.

Rivotril®

Active ingredient(s): *clonazepam*

Consumer Medicine Information (CMI)

This leaflet provides important information about using Rivotril®. **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 Rivotril®.**

Where to find information in this leaflet:

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

1. Why am I using Rivotril®?

Rivotril® contains the active ingredient clonazepam. Rivotril® belongs to a group of medicines called benzodiazepines. They are thought to work by their action on brain chemicals.

Rivotril® drops and tablets are used for the treatment of epilepsy in infants, children and adults.

Rivotril® injection is also used to treat status epilepticus (prolonged or repeated fits or seizures without any recovery between attacks).

Your doctor, however, may have prescribed Rivotril® for another reason.

2. What should I know before I use Rivotril®?

Warnings

Do not use Rivotril® if:

- you are allergic to clonazepam or have had an allergic reaction to Rivotril®, any other benzodiazepine medicine or any ingredients listed at the end of this leaflet.
Some symptoms of an allergic reaction may include:
 - shortness of breath
 - wheezing or difficulty in breathing
 - swelling of the face, lips, tongue or other parts of the body
 - rash, itching or hives on the skin.
- you have severe and chronic lung disease.
- you have severe liver disease.
- you have an addiction to drugs or alcohol.
- the package is torn or shows signs of tampering.
- the expiry date (EXP) printed on the pack has passed.
If you take this medicine after the expiry date has passed it may not work as well.

Rivotril® injection contains benzyl alcohol and must not be given to newborn babies, especially premature babies.

WARNING: Rivotril® Oral liquid must be administered as DROPS only. Refer to section below for more information in Section 4 How do I use Rivotril®?.

This medicine may be addictive. The risks are greater for patients on higher doses or on long term treatment, or patients who have a history of alcohol or drug abuse.

Check with your doctor if you:

- if you are pregnant or plan to become pregnant.
- if you are breastfeeding or plan to breastfeed.
- have any other medical conditions including:
 - liver, kidney or lung disease
 - high or low blood pressure
 - myasthenia gravis (severe muscle weakness)
 - sleep apnoea (a condition where you have temporary stops in breathing during sleep)
 - glaucoma (a condition where you have high pressure in the eye)
 - depression, psychosis or schizophrenia and /or you have had depression or suicidal thoughts in the past.
 - porphyria (a rare blood pigment disorder)
 - ataxia (a condition where you have problems coordinating how your muscle works)
 - a history of alcohol or drug abuse.
- if you drink alcohol.
- if you are galactose or lactose intolerant.
- if you are allergic to any other medicines, foods, dyes or preservatives.
- 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.

Mothers taking more than one medicine to treat their epilepsy may be at greater risk of having a baby with malformation than mothers taking only one medicine for epilepsy. Your baby may develop withdrawal symptoms such as a low body temperature, floppy limbs, feeding problems and breathing difficulties. If there is a need to take Rivotril® when you are pregnant your doctor will discuss the risks and benefits to you and the unborn baby.

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

Rivotril® may pass into the breast milk and cause drowsiness and/or feeding difficulties in the baby. Rivotril® is not recommended for use while breastfeeding.

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 Rivotril® and affect how it works.

- sleeping tablets, sedatives or tranquillisers
- some medicines for depression
- other medicines to control epilepsy
- medicines for allergies or colds such as antihistamines
- pain relievers
- muscle relaxants
- anaesthetics
- cimetidine - a medicine used to treat ulcers
- disulfiram - a medicine used in alcohol abuse

These medicines may be affected by Rivotril® or may affect how well Rivotril® works. Your doctor or pharmacist can tell you what to do if you are taking any of these medicines. They also have a more complete list of medicines to be careful with or avoid while taking Rivotril®.

Taking central nervous system depressants/sedatives

You should not take central nervous system depressants, such as sedatives, tranquilizers, and hypnotics, while taking Rivotril®. These medicines have the potential to increase the effects of Rivotril resulting in severe effects including coma and death.

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

4. How do I use Rivotril®?

How much to take

- Take Rivotril® exactly as your doctor has prescribed.
- Your doctor will tell you how much Rivotril® to take each day.
- The dose varies from person to person depending on age and the condition being treated. Infants and children may need a lower dosage and the use of Rivotril® drops is recommended.
- Follow the instructions provided and use Rivotril® until your doctor tells you to stop.

When to take Rivotril®

- Take Rivotril® as directed by your doctor.
- Rivotril® may be taken with or without food.

How to take Rivotril®

Tablets

- Swallow the Rivotril® tablets whole with a glass of water.

Oral Drops

- **Measure the prescribed dose of Rivotril® Oral liquid as DROPS ONLY.**
Do not administer drops directly into the mouth from the bottle. After each administration, ensure that the dropper is secure in the neck of the bottle. Drops should be given with a spoon. After each opening, make sure the dropper is secured within the neck of the bottle. Rivotril® is compatible with water, tea or fruit juice.

Injections

- Rivotril® injections will be prepared and given by a doctor or nurse.

Caution when administering via infusion:

The active substance can stick to some extent to polyvinyl chloride (PVC), polyurethane (PUR) and silicones. Hence, the use of infusion bags and infusion systems containing any of these materials is not recommended when Rivotril® is administered by infusion.

If you forget to take Rivotril®

Rivotril® should be used regularly at the same time each day. If you miss your dose at the usual time, take it as soon as you remember and 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 are not sure whether to skip the dose, talk to your doctor or pharmacist.

If you take too much Rivotril®

If you think that you have used too much Rivotril®, 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.

If you have taken too much Rivotril®, you may feel drowsy, tired, confused, dizzy, have difficulty breathing, feel weak or become unconscious.

Keep telephone numbers for these places handy.

If you are not sure what to do, contact your doctor or pharmacist.

5. What should I know while using Rivotril®?

Things you should do

Tell all doctors, dentists and pharmacists who are treating you that you are taking Rivotril®.

Do not take any other medicines whether they require a prescription or not without first telling your doctor.

Tell your doctor if you become pregnant while taking Rivotril®.

Tell your doctor if, for any reason, you have not taken your medicine exactly as prescribed.

Otherwise, your doctor may think that it was not effective and change your treatment unnecessarily.

Tell your doctor if you feel Rivotril® is not helping your condition.

Be sure to keep all of your appointments with your doctor so that your progress can be checked.

Your doctor may want to do some blood and other tests from time to time to check on your progress and detect any unwanted side effects.

All mentions of suicide or violence must be taken seriously. Tell your doctor or a mental health professional immediately if you have any suicidal thoughts or other mental/mood changes such as restlessness, aggression, rage, hallucinations or any adverse behavioural effects or unusual behaviour.

Things you should not do

- Do not stop taking Rivotril® or lower the dose without first checking with your doctor. Stopping this medicine suddenly may cause some unwanted effects. Your doctor will explain how you should slowly reduce your dose of Rivotril® before you can stop taking it completely.
- Do not take Rivotril® for a longer time than your doctor has prescribed.
- Do not let yourself run out of medicine over the weekend or on holidays.
- Do not give Rivotril® to anyone else even if they have the same condition as you.
- Do not use Rivotril® to treat other complaints unless your doctor says to.

Things to be careful of

- **Be careful if you are elderly, unwell, or taking other medicines.**
Some people may experience side effects such as drowsiness, confusion, dizziness and unsteadiness which may increase the risk of a fall.
- **If Rivotril® is being given to a young child, you should be especially careful that they are breathing freely.**
Rivotril® may increase the amount of saliva and fluid in the airways of infants and children.

Driving or using machines

Do not drive or use any machines or tools until you know how Rivotril® affects you.

Rivotril® may cause drowsiness or dizziness in some people and therefore may affect alertness.

Make sure you know how you react to Rivotril® before you drive a car or operate machinery or do anything else that could be dangerous if you are drowsy, dizzy or not alert.

Drinking alcohol

Tell your doctor if you drink alcohol.

You should not drink alcohol while taking Rivotril®. Alcohol may increase the effects of Rivotril® and lead to serious side effects, resulting in coma or death.

Looking after your medicine

- Keep your tablets in the blister foil to protect from light until it is time to take them. If you take the tablets out of the blister foil they may not keep well.
- Keep Rivotril® tablets in a cool dry place where the temperature stays below 30°C.
- Keep Rivotril® drops in a cool dry place where the temperature stays below 25°C.
- Rivotril® injection will be stored appropriately by the health care facility where you are treated.

Follow the instructions in the carton 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.

When to discard your medicine

If your doctor tells you to stop taking Rivotril®, or the medicine has passed its expiry date, ask your pharmacist what to do with any tablets that are left over.

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.

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are taking Rivotril®.

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">drowsiness, tirednessdizziness, unsteadinessmuscle weaknesstremorloss of memory, inattentiveness, confusion, lack of concentrationheadache, hangover feeling in the morningslurred speechunpleasant dreamspalpitationsvomitingincreased saliva in infants and childrenchest congestiondouble vision	Tell your doctor if you notice any of the following and they worry you.

Serious side effects

Serious side effects	What to do
<ul style="list-style-type: none">difficulties in breathingchest pain which may spread to your neck and shoulders and down your left armmore fits than usualsudden anxiety or excitationhallucinations or delusionssevere sleep disturbancesdepression, thoughts of self-harmsevere withdrawal symptoms following discontinuation of Rivotril® (including psychological disturbances such as delusional beliefs, feeling outside oneself, confusion, delirium, psychosis)	Call your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you notice any of these serious side effects. Serious side effects are rare.

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 Rivotril® contains

Active ingredient (main ingredient)	Clonazepam
Other ingredients (inactive ingredients)	Tablets: Lactose monohydrate Pregelatinised maize starch Magnesium stearate (470) Pregelatinised potato starch Purified talc (553) Iron oxide red CI 77491 (172) Iron oxide yellow CI 77492 (172) Oral liquid: Saccharin sodium (954) Propylene glycol (1520) Glacial acetic acid (260) Peach flavour PHL-014725 Brilliant blue FCF (C142090) Injection: Ethanol absolute Benzyl alcohol Propylene glycol (1520) Glacial acetic acid (260)
Potential allergens	Tablets contain sugars as lactose.

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

Rivotril® Tablets are gluten free.

What Rivotril® looks like

Rivotril® 0.5 mg tablets are round, pale orange with a score break on one side and marked 0.5 on the other, and come in blister packs of 50 (AUST R 285708).

Rivotril® drops are a clear blue liquid supplied in a 10 mL amber glass bottle with a dropper in the neck of the bottle (AUST R 13758).

Rivotril® injection is a clear, colourless to greenish yellow liquid. It is supplied as a pack of 5 amber glass ampoules (1 mL) with 5 diluent ampoules (1 mL) (AUST R 13757).

Who distributes Rivotril®

Pharmaco (Australia) Ltd

Level 9, Tower A

Zenith Towers

821 Pacific Highway

Chatswood NSW 2067

AUSTRALIA

Phone: 1800 201 564

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