

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 Valium?

Valium contains the active ingredient diazepam. Valium is used for anxiety, to relax muscles, to treat trembling, confusional states or anxiety associated with alcohol withdrawal, and to treat panic attacks. For more information, see Section 1. Why am I using Valium? in the full CMI.

2. What should I know before I use Valium?

Do not use if you have ever had an allergic reaction to Valium, any other benzodiazepine medicine, or any of the ingredients listed at the end of the CMI. The use of Valium may lead to dependence on the medicine. **Talk to your doctor if you have any other medical conditions, have drug or alcohol addiction, drink alcohol, 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 Valium? in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with Valium 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 Valium?

- Take Valium exactly as your doctor has prescribed. Your doctor will tell you how many Valium tablets to take each day.
- The usual adult dose is between 5 and 40 mg daily. Children, elderly and very ill patients may need to take less.
- Valium should be taken for short periods only (for example, 2-4 weeks), unless advised by your doctor.

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

5. What should I know while using Valium?

Things you should do	 Remind any doctor, dentist or pharmacist you visit that you are using Valium. Do not take any other medicines without first telling your doctor. Call your doctor straight away if you become pregnant while taking Valium.
Things you should not do	 Do not take Valium for a longer time than your doctor has prescribed. Do not stop taking Valium or lower the dose without first checking with your doctor, especially if you have epilepsy. Do not let yourself run out of medicine over the weekend or on holidays.
Driving or using machines	Do not drive or operate machinery until you know how Valium affects you.
Drinking alcohol	Alcohol may increase the effects of Valium. Your doctor may suggest that you avoid alcohol or reduce the amount of alcohol you drink while you are using Valium.
Looking after your medicine	 Store below 30°C. Store in a cool, dry place away from young children.

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

6. Are there any side effects?

Call your doctor straight away or go straight to the Emergency Department at your nearest hospital if you notice any of the following serious side effects: sudden anxiety or excitation, restlessness, agitation, irritability, anger, abnormal behaviour, hallucinations, delusions, severe sleep disturbances, or difficulties in breathing, choking or coughing. Speak to your doctor if you have any of the following less side effects and they worry you: drowsiness, tiredness, dizziness, unsteadiness, loss of memory, inattentiveness, confusion, lack of concentration, headache, hangover feeling in the morning, slurred speech, or unpleasant dreams. For more information, including what to do if you have any side effects, see Section <u>6. Are there any side effects?</u> in the full CMI.



Active ingredient: diazepam

Consumer Medicine Information (CMI)

This leaflet provides important information about using Valium. 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 Valium.

Where to find information in this leaflet:

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

1. Why am I using Valium?

Valium contains the active ingredient diazepam. Valium belongs to a group of medicines called benzodiazepines, which are thought to work by their action on brain chemicals. Valium is used for anxiety. Anxiety or tension associated with the normal stress of everyday life usually does not require treatment with medicines. Valium is also used to relax muscles, and can also be used to treat trembling, confusional states or anxiety associated with alcohol withdrawal. It is also used to treat panic attacks.

2. What should I know before I use Valium?

Warnings

Do not use Valium if:

- you are allergic to diazepam, any other benzodiazepine medicine, or any of the ingredients listed at the end of this leaflet. Always check the ingredients to make sure you can use this medicine.
- you have severe and chronic lung disease
- you have severe liver disease
- you have temporary stops in breathing during sleep
- you suffer from severe muscle weakness
- you have drug or alcohol addiction

Check with your doctor if you:

- have any other medical conditions, including:
 - o liver, kidney or lung disease
 - o high or low blood pressure
 - o glaucoma (high pressure in the eye)
 - o depression, schizophrenia or other mental illness
 - o epilepsy (fits)
 - history of alcohol or drug abuse
- take any medicines for any other condition
- drink alcohol. Alcohol may increase the effects of Valium

 Are allergic to any other medicines, foods, dyes or preservatives.

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.

It is not known whether Valium is harmful to an unborn baby when taken by a pregnant woman. If there is a need to take Valium 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.

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

Use in children

 Do not give Valium to children under the age of six months.

Dependence

• The use of benzodiazepines (such as Valium) may lead to dependence on 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.

Some medicines may interfere with Valium and affect how it works, and some medicines may be affected by Valium. These medicines include:

- other sleeping tablets, sedatives or tranquillisers
- medicines for depression
- medicines to control fits
- medicines for allergies or colds such as antihistamines
- pain relievers
- muscle relaxants
- cimetidine and omeprazole- a medicine used to treat
- disulfiram a medicine used in alcohol abuse
- cisapride a medicine used to treat gastric reflux
- ketoconazole a medicine used to treat fungal infections

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

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4. How do I use Valium?

How much to take

- Take Valium exactly as your doctor has prescribed.
 Your doctor will tell you how many Valium tablets to take each day. The dose varies from person to person depending on age and the condition being treated.
- The usual adult dose is between 5 and 40 mg daily.
 Children, elderly and very ill patients may need to take less.
- Valium should be taken for short periods only (for example, 2-4 weeks). Continuous long-term use is not recommended unless advised by your doctor.
- Follow the instructions provided and take Valium until your doctor tells you to stop.

When to take Valium

 Valium can be taken up to three times a day. Your doctor will tell you how much you need to take.

How to take Valium

- Tablets should be swallowed whole with a glass of water
- The tablets can be taken with or without food.

If you forget to use Valium

Valium should be used regularly at the same time each day.

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 use too much Valium

If you think that you have used too much Valium, you may need urgent medical attention. If you have taken too much Valium, you may feel drowsy, tired, confused, dizzy, have difficulty breathing, feel weak or become unconscious.

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 Valium?

Things you should do

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

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

Call your doctor straight away if you:

become pregnant while taking Valium

- have not taken your medicine exactly as prescribed
- you feel the tablets are not helping your condition

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

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

Things you should not do

- Do not take Valium for a longer time than your doctor has prescribed. Valium should be taken for short periods only (for example, 2-4 weeks) unless advised by your doctor.
- Do not stop taking Valium 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 Valium before you can stop taking it completely.
- Do not let yourself run out of medicine over the weekend or on holidays.
- Do not suddenly stop taking Valium if you suffer from epilepsy. Stopping this medicine suddenly may make your epilepsy worse.
- Do not give Valium to anyone else even if their symptoms seem similar to yours.
- Do not use Valium 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.

Avoid drinking grapefruit juice as it may affect the absorption of Valium.

Driving or using machines

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

Valium may cause drowsiness or dizziness in some people and therefore may affect alertness. Make sure you know how you react to Valium 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.

Alcohol may increase the effects of Valium. Your doctor may suggest that you avoid alcohol or reduce the amount of alcohol you drink while you are taking Valium.

Looking after your medicine

 Keep your tablets in the original packaging until it is time to take them.

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

Store it in a cool dry place where the temperature stays below 30°C, 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
Neurological or brain-related: drowsiness, tiredness dizziness, unsteadiness loss of memory, inattentiveness, confusion, lack of concentration headache, hangover feeling in the morning slurred speech unpleasant dreams	Speak to your doctor if you have any of these less serious side effects and they worry you.

Serious side effects

Serious side effects	What to do
Neurological or brain-related: sudden anxiety or excitation restlessness, agitation, irritability, anger, abnormal behaviour hallucinations or delusions severe sleep disturbances Respiratory or breathing-related: Difficulties in breathing or choking or coughing	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.

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 Valium contains

Active ingredient	Diazepam
(main ingredient)	
Other ingredients	lactose monohydrate
(inactive	maize starch
ingredients)	magnesium stearate (470)
	iron oxide yellow CI 77492 (172)
Potential allergens	None.
	Valium tablets are gluten-free.

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

What Valium looks like

Valium tablets are round, yellow with a score break and 5 V on one side (Aust R 48566).

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Valium comes in a pack of 50 tablets.

Who distributes Valium

Clinect Pty Ltd

120-132 Atlantic Drive

Keysborough VIC 3173, Australia

Free Call Australia: 1800 899 005

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Valium[®]