

pronounced (val-i-um)

contains the active ingredient diazepam

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about VALIUM.

It does not contain all the available information.

It does not take the place of talking to your doctor or pharmacist.

All medicines have risks and benefits. Your doctor has weighed the risks of you taking VALIUM against the benefits they expect it will have for you.

If you have any concerns about taking this medicine, ask your doctor or pharmacist.

Keep this leaflet with the medicine.

You may need to read it again.

What VALIUM is used for

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 used to relax muscles.

VALIUM can also be used to treat trembling, confusional states or anxiety associated with alcohol

withdrawal. It is also used to treat panic attacks.

VALIUM belongs to a group of medicines called benzodiazepines. They are thought to work by their action on brain chemicals.

Benzodiazepines are not recommended as the only treatment of severe mental illnesses and should not be used alone to treat depression.

Your doctor, however, may have prescribed VALIUM for another purpose.

Ask your doctor if you have any questions about why VALIUM has been prescribed for you.

In general, benzodiazepines such as VALIUM should be taken for short periods only (around 2 to 4 weeks). Continuous long term use is not recommended unless advised by your doctor.

The use of benzodiazepines may lead to dependence on the medicine.

This medicine is available only with a doctor's prescription.

Before you take VALIUM

Do not take VALIUM if:

- 1) **you have had an allergic reaction to VALIUM, any other benzodiazepine medicine or any ingredients listed at the end of this leaflet**

- 2) **you have severe and chronic lung disease**
- 3) **you have severe liver disease**
- 4) **you have temporary stops in breathing during sleep**
- 5) **you suffer from severe muscle weakness**
- 6) **you have drug or alcohol addiction**
- 7) **the packaging is torn or shows signs of tampering**
- 8) **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.

If you are not sure whether you should be taking VALIUM, talk to your doctor.

Do not give VALIUM to children less than six months old.

Before you start to take it:

Your doctor must know about all the following before you start to take VALIUM.

- 1) **if you are pregnant or plan 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.
- 2) **if you are breastfeeding or plan 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.

3) if you have any other health problems including:

- liver, kidney or lung disease
- high or low blood pressure
- glaucoma (high pressure in the eye)
- depression, schizophrenia or other mental illness
- epilepsy (fits)

4) if you drink alcohol

Alcohol may increase the effects of VALIUM.

5) if you are allergic to any other medicines, foods, dyes or preservatives.

Taking other medicines

Tell your doctor if you are taking any other medicines including any that you have bought without a prescription from a pharmacy, supermarket or healthfood shop.

Some medicines may interfere with VALIUM. These medicines include:

- other sleeping tablets, sedatives or tranquillisers
- medicines for depression
- medicines to control fits
- medicines for allergies or colds eg. antihistamines
- pain relievers
- muscle relaxants
- cimetidine and omeprazole- a medicine used to treat ulcers
- disulfiram - a medicine used in alcohol abuse

- cisapride-a medicine used to treat gastric reflux
- ketoconazole- a medicine used to treat fungal infections

These medicines may be affected by VALIUM or may affect how well VALIUM 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 VALIUM.

If you are taking any other medications, check with your doctor before you start to take VALIUM.

How to take 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.

How to take it

Tablets should be swallowed whole with a glass of water.

When to take it

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

The tablets can be taken with or without food.

How long to take VALIUM

Usually, 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. The use of benzodiazepines may lead to dependence on the medicine.

Continue taking VALIUM until your doctor tells you to stop.

If you forget to take VALIUM

If it is almost time for your next dose, skip the dose you missed and take your next dose when you are meant to. Otherwise, take it as soon as you remember and then go back to taking it as you would normally.

Do not double a dose to make up for one you have missed.

If you are not sure whether to skip the dose, talk to your doctor or pharmacist.

In case of an overdose

Immediately telephone your doctor or Poisons Information Centre (telephone 13 11 26) for advice or go to Accident and Emergency at your nearest hospital if you think that you or anyone else may have taken too much VALIUM, even if there are no signs of discomfort or poisoning.

You may need urgent medical attention.

Keep telephone numbers for these places handy.

If you have taken too much VALIUM, you may feel drowsy, tired, confused, dizzy, have

difficulty breathing, feel weak or become unconscious.

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

While you are taking VALIUM

Things you must 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.

Tell your doctor if you become pregnant while taking VALIUM.

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 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.

Things you must not do

Do not drive or operate machinery 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 your

drive a car or operate machinery or do anything else that could be dangerous if you are drowsy, dizzy or not alert.

Do not take VALIUM for a longer time than your doctor has prescribed. VALIUM should be taken for short periods only (for example 2 to 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 when drinking alcohol while taking VALIUM.

Combining VALIUM and alcohol can make you more sleepy, dizzy or lightheaded. Your doctor may suggest that you avoid alcohol or reduce the amount of alcohol you drink while you are taking VALIUM.

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.

Side Effects

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

VALIUM helps most people with anxiety but it may have unwanted side effects in a few. All medicines can have side effects. Sometimes they are serious, most of the time they are not. Some side effects may require medical treatment.

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

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

- drowsiness, tiredness
- dizziness, unsteadiness
- loss of memory, inattentiveness, confusion, lack of concentration
- headache, hangover feeling in the morning
- slurred speech
- unpleasant dreams

Tell your doctor immediately or go to casualty at your nearest hospital if you notice any of the following:

- sudden anxiety or excitation
- restlessness, agitation, irritability, anger, abnormal behaviour
- hallucinations or delusions
- severe sleep disturbances

- difficulties in breathing or choking or coughing

These are serious side effects. You may need urgent medical attention. Serious side effects are rare.

This is not a complete list of all possible side effects. Others may occur in some people and there may be some side effects not yet known.

Tell your doctor if you notice anything else that is making you feel unwell, even if it is not on this list.

Ask your doctor or pharmacist if you don't understand anything in this list.

Do not be alarmed by this list of possible side effects. You may not experience any of them.

After taking VALIUM

Storage

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

If you take the tablets out of the blister pack they may not keep well.

Keep VALIUM in a cool dry place where the temperature stays below 30°C.

Do not store it, or any other medicine, in a bathroom or near a sink.

Do not leave it in the car or on window sills.

Heat and dampness can destroy some medicines.

Keep VALIUM where children cannot reach it.

A locked cupboard at least one-and-a-half metres above the ground is a good place to store medicines.

Disposal

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

Product Description

What VALIUM looks like

VALIUM 2 mg Tablets are round, white with a score break and Roche 2 on one side.

VALIUM 5 mg Tablets are round, yellow with a score break and Roche 5 on one side.

Ingredients

Active ingredient - diazepam

- each 2 mg tablet contains 2 mg diazepam
- each 5 mg tablet contains 5 mg diazepam

Inactive ingredients -

- both 2 mg and 5 mg tablets contain lactose, maize starch and magnesium stearate (470).
- the 5 mg tablets also contain the colouring iron oxide yellow, CI 77492 (172)

VALIUM tablets are gluten free

VALIUM 2 mg Tablets come in packs of 50.

VALIUM 5 mg Tablets come in packs of 50.

Manufacturer

VALIUM is distributed by:

Roche Products Pty Limited
ABN 70 000 132 865
4 - 10 Inman Road
Dee Why NSW 2099
AUSTRALIA

Customer enquiries: 1 800 233 950

Please check with your pharmacist for the latest Consumer Medicine Information.

Australian Registration Number

- VALIUM 2 mg Tablets
AUST R 66129
- VALIUM 5 mg Tablets
AUST R 48566

This leaflet was prepared on 18 February 2010