

PATIENT INFORMATION LEAFLET

SCHEDULING STATUS: S5

VALIUM® 10 mg/2 mL injection

Diazepam

Sugar free

Read all of this leaflet carefully before you are given VALIUM

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor, pharmacist, nurse or healthcare provider.
- VALIUM has been prescribed for you personally and you should not share your medicine with other people. It may harm them, even if their symptoms are the same as yours.

What is in this leaflet

1. What VALIUM is and what it is used for
2. What you need to know before you are given VALIUM
3. How VALIUM will be given to you
4. Possible side effects
5. How to store VALIUM
6. Contents of the pack and other information

1. What VALIUM is and what it is used for

What VALIUM is

VALIUM is a long-acting benzodiazepine hypnotic with anxiolytic, sedative, muscle-relaxant, anticonvulsant and amnesic properties.

What VALIUM is used for

VALIUM is indicated for the following conditions:

- Conscious sedation (an awake but very relaxed state of calm or drowsiness during a medical test or procedure).
- Premedication (medicine used to cause relaxation, calm and drowsiness before an anaesthetic).
- The treatment of acute anxiety and panic, as well as trembling and anxiety associated with alcohol withdrawal.
- The treatment of epilepsy and other convulsive states (including tetanus).
- The treatment of seizures in eclampsia (a condition that may occur during pregnancy), only if a medicine called magnesium sulphate is not indicated or did not work well enough.
- Used to relieve severe muscle spasm.

2. What you need to know before you are given VALIUM

You should not be given VALIUM:

- If you are allergic (hypersensitive) to VALIUM or any other benzodiazepine medicine (e.g. clonazepam, flurazepam and temazepam) or any of the other ingredients in VALIUM.
- If you have breathing or lung problems.
- If you have severe liver problems as benzodiazepines may cause brain decline due to liver disease.
- If you have a condition called “sleep apnoea syndrome” (where your breathing stops when you are asleep).
- If you have a condition called “myasthenia gravis” (where your muscles are weak and get tired easily).
- If you have problems with phobias (strong fears) or obsessions (troublesome, unwanted and repeated thoughts, ideas or feelings).

- If you are treated for any mental illness or psychosis.
- If you suffer from depression or suicidal thoughts.
- If you are taking any other central nervous system medication, alcohol or if you are an alcoholic.

Tell your doctor or healthcare professional before being given the injection if the above applies to you.

If you are not sure, talk to your doctor or pharmacist before being given VALIUM.

Warnings and precautions

Talk to your doctor or pharmacist before being given VALIUM:

- If you regularly drink alcohol and/or CNS depressants, or take recreational drugs.
- If you have had problems with alcohol or drug abuse in the past.
- If you are driving a car and/or operating machinery.
- If you have liver, kidney, lung or heart problems.
- If you are being treated for depression.
- If VALIUM is to be given to a child younger than 6 months of age. VALIUM is not recommended for use in this age group unless there are no other treatment options.
- If you are elderly or very ill, your doctor will decide whether to inject you with a lower dose of VALIUM.

If any of the above apply to you, or if you are not sure, talk to your doctor or pharmacist before you are given VALIUM.

Other medicines and VALIUM

Always tell your healthcare professional if you are taking any other medicine. (This includes complementary or traditional medicines).

VALIUM can affect the way some medicines work. Also some medicines can affect the way VALIUM works.

In particular, tell your doctor or pharmacist if you are taking any of the following medicines:

- Medicines to treat mental health problems such as antidepressants.

- Medicines to relieve anxiety such as other benzodiazepine medicines (clonazepam, flurazepam and temazepam).
- Medicines to help you sleep.
- Medicines to treat convulsions or epilepsy such as phenytoin or carbamazepine.
- Strong pain killers, such as morphine, pethidine and methadone.
- Medicines for allergies, which make you sleepy and act on the central nervous system.
- Medicines to treat stomach problems and heartburn, such as cimetidine, cisapride, metoclopramide or omeprazole.
- Medicines to treat fungal infections, such as fluconazole and voriconazole.
- Medicines for birth control.
- A medicine used to treat alcohol abuse, disulfiram.
- A medicine to treat high blood pressure known as diltiazem.
- Medicines used to treat tuberculosis such as isoniazid and rifampicin.
- A medicine used to treat certain blood cancers known as idelalisib.
- Medicines to treat sleepiness such as modafinil and armodafinil.
- Medicines to treat psychiatric conditions known as clozapine, levomepromazine and olanzapine.
- Medicines used to treat Parkinson's disease known as levodopa.

Concomitant use of VALIUM and opioids (strong pain killers, medicines for substitution therapy and some cough medicines) increases the risk of drowsiness, difficulties in breathing (respiratory depression), coma and may be life-threatening.

Because of this, concomitant use should only be considered when other treatment options are not possible.

Anaesthetics: If you are going to have an anaesthetic for an operation or dental treatment, it is important to tell your doctor or dentist that you are taking VALIUM.

VALIUM with food and drink

Drinking alcohol: Do not drink alcohol while you are being given VALIUM, because VALIUM can make you sleepy. You are more likely to have problems with your concentration and to fall more deeply asleep which may cause serious problems with your breathing or heartbeat.

Pregnancy and breastfeeding

If you are pregnant, trying to get pregnant or breastfeeding your baby please consult your doctor, pharmacist or other healthcare professional for advice before being given VALIUM.

Your doctor will decide if you should be given VALIUM. This is because VALIUM will affect your baby.

If you are already being given VALIUM talk to your doctor immediately, he will decide if you should stop receiving it.

Do not breast feed your baby while taking VALIUM.

Driving and using machines

Talk to your doctor before about driving or using tools or machines, while you are being given VALIUM.

This is because VALIUM can make you sleepy, making it difficult to concentrate and slow down your reactions. You should also read the section on “Drinking alcohol”. If you are in any doubt about whether you can do a particular activity, talk to your doctor.

VALIUM contains benzyl alcohol

VALIUM Injection contains benzyl alcohol and can cause serious adverse events in newborn babies, especially premature ones. Your doctor will decide whether VALIUM is the only option for treatment or not.

3. How VALIUM will be given to you

You will not be expected to give yourself VALIUM. It will be given to you by a person who is qualified to do so.

Always receive VALIUM exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure.

VALIUM Injection: your doctor will decide how much VALIUM to inject or infuse.

The usual dose is 2 - 20 mg, depending on bodyweight, indication and severity of symptoms administered intramuscularly or intravenously.

- If you are elderly or very ill or have problems with your liver or kidneys, your doctor may give you a lower dose.
- Children's dose: Your doctor will prescribe the correct dose for your child, according to your child's weight and severity of his/her illness.

If you have the impression that the effect of VALIUM is too strong or too weak, talk to your doctor or pharmacist.

If you receive more VALIUM than you should

Since a healthcare professional will administer the VALIUM, he/she will control the dosage. However, in the event of overdosage your doctor will manage the overdose.

4. Possible side effects

VALIUM can have side effects.

Stop taking VALIUM and see a doctor straight away if you notice any of the following serious side effects – you may need urgent medical treatment:

- Chest pain which may spread to your neck and shoulders and down your left arm. This may be a sign of a heart attack.
- Breathing problems (respiratory depression). Early signs include sudden noisy, difficult and uneven breathing. Your skin may become blue.
- A feeling of fullness in your bladder and urge to pass water, but then difficulty emptying your bladder.
- Being restless, aggressive, angry, irritable or agitated.

- Nightmares and seeing or hearing things that are not really there (hallucinations).
- Mental problems such as delusions (believing in things that are not real) or losing contact with reality.
- A change in your behaviour that is out of character.

Not all side effects reported for VALIUM are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking this medicine, consult your doctor, pharmacist or other healthcare professional for advice.

The following effects may occur at any time during your treatment:

Frequent:

- Feeling tired.
- Weak muscles.

Mind and nervous system

Less frequent:

- Poor co-ordination, including feeling unsteady when you walk.
- Slow or slurring of speech.
- Headache.
- Feeling dizzy.
- Uncontrollable movements, for example of your hands (tremor).
- Anterograde amnesia (difficulty remembering new things).
- Confusion.
- Mood disturbances.
- Depression.
- Being less alert.
- Nervousness.
- Anxiety.
- Abnormal dreams.

- Hyperactivity.

Heart and circulation

Less frequent:

- Low blood pressure. The signs include feeling dizzy or light-headed.
- Uneven heartbeat.

Stomach and gut

Less frequent:

- Feeling sick (nausea).
- Constipation.
- Dry mouth.
- More saliva in your mouth than usual.

Sexual

Less frequent:

- A higher or lower interest in sex.

Eyes and ears

Less frequent:

- Problems with your eye-sight, including double or blurred vision.
- Vertigo. The signs include feeling dizzy or a spinning sensation.

Skin

Less frequent:

- Skin rashes.

Liver and kidneys

Less frequent:

- Changes in how well your liver is working (shown by blood tests).
- Loss of bladder control (wetting yourself).

Injury

Less frequent:

When you take VALIUM you are at risk of falling and breaking your bones. This risk is increased if you are elderly or are taking other sedatives (including alcohol).

Withdrawal symptoms:

You can become dependent on benzodiazepine medicines like VALIUM. This means that if you stop treatment suddenly, or lower the dose too quickly, you may get withdrawal symptoms. The symptoms can include:

Frequent withdrawal symptoms include:

- Headache.
- Diarrhoea.
- Muscle pain and feeling restless.
- Feeling very worried, tense, confused or bad tempered.

Less frequent withdrawal symptoms include:

- Feeling sensitive to light, noise and touch.
- Seeing or hearing things that are not really there (hallucinations).
- Tingling and numb in your arms and legs.
- Feeling lost or losing contact with reality.
- Fits (seizures).

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

Reporting of side effects

Reporting suspected adverse reactions after authorisation of the medicine is important. It allows continued monitoring of the benefit/risk balance of the medicine. Health care providers are requested to report any suspected adverse drug reactions to SAHPRA via the Med Safety APP (Medsafety X SAHPRA) and eReporting platform (who-umc.org) found on SAHPRA website.

5. How to store VALIUM

Store all medicines out of reach of children.

Store at or below 30 °C. Keep in outer carton until required for use.

Do not use this medicine after the expiry date shown on the label.

If your doctor decides to stop the treatment, return any leftover ampoules to the pharmacist. Only keep them if your doctor tells you to. Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

6. Contents of the pack and other information

What VALIUM contains

Injection in Ampoules

Each ampoule contains 10 mg diazepam per 2 mL.

The other ingredients are:

Benzyl alcohol, benzoic acid, sodium benzoate, ethyl alcohol, propylene glycol, sodium hydroxide and water for injection.

VALIUM injection contains 8,5 % ethyl alcohol. Contains benzyl alcohol as a vehicle.

What VALIUM looks like and contents of the pack

VALIUM 10 mg/2 mL injection: Greenish yellow solution in 2 mL colourless glass ampoules.

VALIUM 10 mg/2 mL: 5's

Holder of Certificate of Registration

Pharmaco Distribution (Pty) Ltd.

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Ethical assistance Line: +27 (0) 11 784 00 77

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Registration numbers

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NAMIBIA Reg. No. 90/2.6/001433	NS3