

PRODUCT MONOGRAPH

 **VALIUM**[®]

diazepam

5 mg Tablets

Anxiolytics:
Benzodiazepine derivatives

Hoffmann-La Roche Ltd.
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Mississauga, Ontario
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Table of Contents

PART III: CONSUMER INFORMATION.....3

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 **VALIUM**[®]
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This leaflet is a part of the "Product Monograph" published for VALIUM and is designed specifically for Consumers.

Please read this information before you start to take your medicine. Keep this leaflet until you have finished all your tablets, as you may need to read it again. If you are helping someone else to take VALIUM, read this leaflet before you give the first tablet.

This leaflet is a summary and will not tell you everything about VALIUM. Contact your doctor or pharmacist if you have any questions about the drug.

ABOUT THIS MEDICATION**What the medication is used for:**

- VALIUM is used for the short-term relief of severe anxiety.
- VALIUM is used to reduce muscle spasms caused by medical conditions such as local trauma or by disorders such as cerebral palsy, paraplegia and "stiff man syndrome".
- VALIUM can also be used to treat trembling, confusional states or anxiety associated with alcohol withdrawal

What it does:

VALIUM contains the active ingredient diazepam, which belongs to a group of medicines known as benzodiazepines. VALIUM has sedative properties which help in the treatment of anxiety.

When it should not be used:

- If you are allergic to the group of medicines known as benzodiazepines (examples: clonazepam, chlordiazepoxide, bromazepam, or flurazepam).
- If you are allergic to the medicinal ingredient (diazepam)
- If you are allergic to any of the other ingredients it contains (see 'What the non-medicinal ingredients are').
- If you suffer from lung disease or have sleep apnea.
- If you have a liver condition.
- If you have glaucoma.
- If you have myasthenia gravis.
- In children under 6 months.

What the medicinal ingredient is:

Diazepam

What the non-medicinal ingredients are:

Corn starch, iron oxide yellow, lactose, magnesium stearate.

What dosage forms it comes in:

Tablets, 5 mg (pale yellow), cylindrical tablet, with ROCHE 5 engraved on one face and a single score on the other.

WARNINGS AND PRECAUTIONS**Serious Warnings and Precautions**

Taking VALIUM with opioid medicines can cause severe drowsiness, decreased awareness, breathing problems, coma and death.

- VALIUM may affect your ability to be alert. Driving, operating machinery and other hazardous activities should therefore be avoided altogether or at least during the first few days of treatment. This effect of VALIUM may be made worse if you take alcoholic drinks. If your doctor has increased your dose or if you have changed the timings of when you take your medication this may also modify your reactions.
- You must not consume alcohol or other drugs that affect the central nervous system while taking VALIUM (see INTERACTIONS WITH THIS MEDICATION below).
- Always contact your doctor before stopping or reducing your dosage of VALIUM, as suddenly stopping treatment or a large decrease in dose can cause withdrawal symptoms.
- Benzodiazepines such as VALIUM have produced dependence (addiction) and withdrawal symptoms can occur when treatment is stopped suddenly or switched to another benzodiazepine. The risk of dependence (addiction) increases with higher doses and longer duration of treatment. Symptoms of withdrawal may include shaking, sweating, sleep disturbances, agitation/restlessness, headache, muscle pain, anxiety, confusion, and irritability. In severe cases of withdrawal, symptoms may include numbness and tingling of the extremities, hallucinations (see or hear things that are not there), increased sensitivity to light, noise and physical contact, and seizures.
- There have been reports of falls and fractures in people who take benzodiazepines such as VALIUM. The risk is increased in those also taking other sedatives (including alcoholic beverages) and in the elderly.
- Memory loss may occur when VALIUM is used at therapeutic doses.
- If you develop any unusual or disturbing thoughts or behaviour while using VALIUM, discuss the matter immediately with your doctor.
- Do not take this medicine if you are pregnant, or might become pregnant, unless advised by your doctor. Contact your doctor if you think you may be pregnant, or are intending to become pregnant.

- VALIUM passes into breast milk. Therefore, if you are breast feeding, this medicine should be avoided. Your doctor will discuss this with you.

BEFORE you use VALIUM talk to your doctor or pharmacist if you:

- Have a lung, liver or kidney condition.
- Have glaucoma.
- Are taking or plan on taking ANY other drugs (including herbal preparations, drugs you purchase without prescriptions, and those not prescribed by your doctor).
- Regularly drink alcohol or use recreational drugs or have a history of dependence /addiction to alcohol or drugs.
- Have a history of depression and/or suicide attempts.
- Have the rare hereditary problems of galactose intolerance.
- Are pregnant or plan on becoming pregnant.

- medications to treat psychosis (methotrimeprazine, clozapine, olanzapine)
- medications to treat Parkinson’s disease (levodopa)
- medications to help you stay awake (theophylline and caffeine)

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.

You must not consume alcohol while taking VALIUM as its effects may worsen side effects that some patients experience with VALIUM.

Do not drink grapefruit juice during the time that you are taking VALIUM.

If you have not told your doctor about any of the above, tell him/her before you start taking VALIUM.

INTERACTIONS WITH THIS MEDICATION

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

Some medicines may interact with VALIUM. These medicines include:

- medicines to control seizures (flumazenil, carbamazepine, phenytoin)
- narcotics and narcotic pain relievers (opioids) (see **Serious Warnings and Precautions** box)
- muscle relaxants
- sleeping medication or hypnotics (ketamine)
- antihistamines or allergy medications.
- medications to control fungus infections (ketoconazole, itraconazole, fluconazole and voriconazole)
- medications to control viral infections (ritonavir)
- birth control medications
- medications to help digestion, prevent heartburn (such as antacids omeprazole or esomeprazole) or treat ulcers (cimetidine)
- medications to treat cancer of the blood (idelalisib)
- medications to treat addiction to drugs (methadone, buprenorphine) or alcohol (disulfiram)
- antibiotic medications to treat bacterial infections, including tuberculosis (clarithromycin, erythromycin, isoniazid, rifampicin)
- medications used to treat high blood pressure (diltiazem, verapamil)
- medications used to treat narcolepsy and shift work disorder (modafinil, sodium oxybate)
- medicines to treat your anxiety or mood, such as monoamine oxidase inhibitors, tricyclic antidepressants, serotonin specific reuptake inhibitors (fluvoxamine, fluoxetine)

PROPER USE OF THIS MEDICATION

Usual dose:

Always take the tablets exactly as your doctor tells you to. Your doctor will prescribe a suitable dose for you. The dose your doctor prescribes will depend on the nature of your illness, your reaction to the medicine, your age and body weight. The table below shows the different doses that your doctor may prescribe according to your age. Your doctor will start you on an initial low dose and gradually increase it until the desired effect is achieved.

	Usual Daily Dose
Adults Relief of Severe anxiety and tension	Depending upon severity of symptoms - 2 mg to 10 mg, two to four times daily.
Relief of Acute Alcohol Withdrawal	10 mg, three or four times during the first 24 hours, reducing to 5 mg, three or four times daily as needed.
Relief of severe muscle spasm	2 mg to 10 mg, three to four times daily.
Elderly	2 mg, one or two times daily initially, increase gradually as needed and tolerated
Children (7 months and older)	1 mg to 2.5 mg, three or four times daily initially; increase gradually as needed and tolerated.

The total daily dose should be taken as advised by your doctor.

Do not change the prescribed dose yourself. If you think the effect of your medicine is too weak or too strong, talk to your doctor.

Your doctor will advise you when to stop taking the medicine. Your doctor will slowly decrease the dosage as sudden discontinuation of treatment can cause the appearance of withdrawal symptoms.

Overdose:

In case of drug overdose, contact a health care practitioner, hospital emergency department or regional Poison Control Centre immediately, even if there are no symptoms.

SIDE EFFECTS AND WHAT TO DO ABOUT THEM

Like all medications VALIUM can cause some side effects. For most patients these side effects are likely to be minor and temporary as your body adjusts to the medicine. However, some may be serious. Consult your doctor or pharmacist as soon as you can if you do not feel well while taking VALIUM.

The most common side effects are:

- Feeling drowsy or tired, especially at the start of treatment.
- Some muscle weakness and dizziness.

Less common possible side effects are:

- Changes in your skin colour, nausea, headache, blurred vision, tremors, hypotension (low blood pressure), urinary incontinence, and constipation.
- Memory loss may occur in some patients using VALIUM.
- In rare cases changes in your blood and liver may occur and your doctor will monitor for these.
- Falls and fractures: The risk is increased in those also taking other sedatives (including alcoholic beverages) and in the elderly.

Withdrawal-related side effects:

- With long-term VALIUM treatment development of physical and psychological dependence may occur. If treatment is stopped suddenly symptoms of withdrawal may occur, including: headache, muscle pain, extreme anxiety, tension, restlessness, confusion and irritability. In severe cases of withdrawal, symptoms may include numbness and tingling of the extremities, hallucinations, increased sensitivity to light, noise and physical contact, and epileptic seizures.

SERIOUS SIDE EFFECTS, HOW OFTEN THEY HAPPEN AND WHAT TO DO ABOUT THEM

Symptom / effect		Talk with your doctor or pharmacist		Stop taking drug and seek medical help
		Only if severe	In all cases	
Rare	Unusual behavioural problems (aggression, rage, sudden anxiety or excitation; restlessness, agitation, irritability; hallucinations (see or hear things that are not there) or delusions; severe sleep disturbances, nightmares, inappropriate behaviour		✓	
	Allergic reactions (red skin, hives, itching, swelling of the lips, face, tongue, throat, trouble breathing, wheezing, shortness of breath, skin rashes, blisters of the skin, sores or pain in the mouth or eyes)			✓ Immediately
	Depression. Symptoms may include: difficulty sleeping, changes in weight, feelings of worthlessness, guilt, regret, helplessness or hopelessness, withdrawal from social situations, family gatherings and activities with friends, reduced libido (sex drive), and thoughts of death or suicide.		✓	

This is not a complete list of side effects. If you are concerned about these or any other unwanted side-effects, talk to your doctor or pharmacist.

HOW TO STORE IT

- Keep VALIUM in a cool dry place stored at room temperature (15-30°C).
- Keep this medicine out of sight and reach of children.

REPORTING SUSPECTED SIDE EFFECTS

You can report any suspected adverse reactions associated with the use of health products to the Canada Vigilance Program by one of the following 3 ways:

- Report online at www.healthcanada.gc.ca/medeffect
- Call toll-free at 1-866-234-2345
- Complete a Canada Vigilance Reporting Form and:
 - Fax toll-free to 1-866-678-6789, or
 - Mail to: Canada Vigilance Program
Health Canada
Postal Locator 1908C
Ottawa, Ontario
K1A 0K9

Postage paid labels, Canada Vigilance Reporting Form and the adverse reaction reporting guidelines are available on the MedEffect™ Canada Web site at www.healthcanada.gc.ca/medeffect.

NOTE: Should you require information related to the management of side effects, contact your health professional. The Canada Vigilance Program does not provide medical advice.

MORE INFORMATION

Reminder: This medicine has been prescribed only for you. Do not give it to anybody else. If you have any further questions, please ask your doctor or pharmacist.

This document plus the full product monograph, prepared for health professionals can be found at www.rochecanada.com or by contacting the sponsor, Hoffmann-La Roche Limited, at 1-888-762-4388.

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