

Package leaflet: Information for the patient

Valium® 5 mg Tablets

Roche

Diazepam

Please read all of this leaflet carefully before you start taking this medicine because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What Valium is and what it is used for
2. Before you take Valium
3. How to take Valium
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

Valium contains a medicine called diazepam. This belongs to a group of medicines called ‘benzodiazepines’.

Valium is used to treat anxiety and problems sleeping (insomnia), muscle spasms (cramps) such as those caused by cerebral spasticity, epilepsy (fits), making you relaxed before an operation (premedication).

2. What you need to know before you take Valium

Do not take Valium if you are allergic (hypersensitive) to:

- Diazepam or any of the other ingredients of Valium (listed in Section 6: Contents of the pack and other information).
- Other ‘benzodiazepine’ medicines. These include clonazepam, flurazepam and temazepam.

Do not take Valium if any of the above applies to you. If you are not sure, talk to your doctor or pharmacist before taking Valium.

Do not take Valium if:

- You have breathing or lung problems.
- You have severe liver problems.
- You have a condition called ‘myasthenia gravis’ (where your muscles become weak and get tired easily).
- You have a condition called ‘sleep apnoea syndrome’ (where your breathing stops when you are asleep).
- You have problems with phobias (strong fears) or obsessions (troublesome, unwanted and repeated thoughts, ideas or feelings).
- You have a mental problem (chronic psychosis) which may make you confused, lose contact with reality or become unable to think and judge clearly.

Do not take Valium if any of the above applies to you. If you are not sure, talk to your doctor or pharmacist before taking Valium.

Warnings and precautions

Talk to your doctor or pharmacist before taking Valium if:

- You have liver, kidney or lung problems.
- You are being treated for depression.
- A close friend or relative has recently died.
- You regularly drink alcohol or take recreational drugs.
- You have had problems with alcohol or drug use in the past.

If any of the above applies to you, or if you are not sure, talk to your doctor or pharmacist before taking Valium.

Children

Valium is not recommended for children less than 6 months of age unless there is no other treatment option.

Other medicines and Valium

Please tell your doctor or pharmacist if you are taking, or have recently taken or might take any other medicines. This includes medicines that you buy without a prescription and herbal medicines. This is because Valium can affect the way some other medicines work. Also some other medicines can affect the way Valium works.

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

- Fluvoxamine, fluoxetine or other medicines to treat mental health problems.
- Medicines to help you sleep.
- Medicines for allergies, which make you sleepy.
- Phenytoin or other medicines to treat epilepsy.
- Cimetidine, omeprazole or cisapride (to treat stomach problems and heartburn).
- Ketoconazole (to treat fungal skin infections).
- Strong painkillers (such as morphine).

If any of the above applies to you, or if you are not sure, talk to your doctor or pharmacist before you take Valium.

Operations

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

Valium with alcohol

Do not drink alcohol while you are taking Valium. This is because:

- Valium can make you feel sleepy.
- You are more likely to have problems with your concentration and to fall more deeply asleep.
- If you fall very deeply asleep this may cause serious problems with your breathing and heartbeat.

Pregnancy and breast-feeding

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor for advice before taking this medicine. Your doctor will then decide if you should take Valium. This is because Valium will affect your baby. If you are already taking Valium talk to your doctor immediately, he will decide if you should stop taking this medicine.

Driving and using machines

Talk to your doctor about driving and using tools or machines whilst you are taking Valium. This is because Valium can make you feel sleepy, make it difficult to concentrate and slow down your reactions. You should also read the section on 'Valium with alcohol'. If you are in any doubt about whether you can do a particular activity, talk to your doctor.

Valium contains lactose

This medicine contains lactose, which is a type of sugar. If you have been told by your doctor that you cannot tolerate or digest some sugars (have an intolerance to some sugars), talk to your doctor before taking this medicine.

3. How to take Valium

Always take Valium exactly as your doctor has told you. You should check with your doctor if you are not sure.

- You will be started on a low dose of Valium. Your doctor will slowly increase it until you are taking the right dose for you. Your doctor will give you the lowest possible dose that works for you.
- Your doctor will want you to take Valium for the shortest possible time.

Adults

Treatment for anxiety

- The maximum dose is 30 mg a day, split into several doses.
- You will normally take this medicine for no more than 12 weeks.

Treatment for problems sleeping (insomnia)

- The usual dose is between 5 mg and 15 mg, taken just before going to bed.
- It is important that you have 7 to 8 hours of undisturbed sleep after taking Valium.
- You will normally take this medicine for no more than 4 weeks.

Treatment for muscle spasms (cramps)

- The maximum dose is 15 mg a day, split into several doses.

Treatment for muscle spasms in cerebral spasticity

- The maximum dose is 60 mg a day, split into several doses.

To help you relax before an operation (premedication)

- The usual dose is between 5 mg and 20 mg.

Children (6 months of age and older)

Treatment of muscle spasms in cerebral spasticity in children

- The maximum dose is 40 mg a day, split into several doses.

To help children relax before an operation (premedication)

- The maximum dose is 10 mg.

Children (under 6 months of age)

- Valium should be used in this age group with extreme care (see Section 2 under: 'What you need to know before you take Valium'). The child's doctor will decide how much should be given and how often.

Older people and people with liver problems

Your doctor will decide how many tablets you should take and how often. The amount you take will depend on why you are being treated. Your dose will be lower than the normal dose prescribed for other adults.

If you take more Valium than you should

- If you take more Valium than you should, or if someone else takes your Valium tablets by mistake, talk to a doctor or go to a hospital straight away. Take the medicine pack with you.
- If you take too many tablets, you may feel sleepy, have difficulty controlling your movements (lack of co-ordination), or have slow or slurred speech or jerky eye movements.

If you forget to take Valium

- If you forget to take a dose, skip the missed dose. Then take the next dose when it is due.
- Do not take a double dose (two doses at the same time) to make up for a forgotten dose.

If you stop taking Valium

- Do not stop taking your tablets without talking to your doctor.
- When you stop taking Valium, your anxiety or insomnia may return and you may get withdrawal symptoms, especially if you stop too quickly. For the symptoms you may have see 'Withdrawal symptoms' in Section 4: Possible side effects.
- When it is time to lower your dose or stop taking Valium, it must be done slowly. This lowers the chances of you having withdrawal symptoms. Your doctor will tell you how to do this.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

4. Possible side effects

Like all medicines Valium can cause side effects, although not everybody will get them.

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 suddenly noisy, difficult and uneven breathing. Your skin may become blue.
- A feeling of fullness in your bladder and the 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.

When you start taking Valium you may notice the following effects:

- Feeling tired.
- Weak muscles.

These effects usually go away after some time. If you are worried or unsure, talk to your doctor or pharmacist.

The following effects may occur at any time during your treatment:**Mind and nervous system**

- Poor co-ordination, including feeling unsteady when you walk.
- Slowing or slurring of speech.
- Headache.
- Feeling dizzy.
- Uncontrollable movements, for example of your hands (tremor).
- Difficulty remembering new things.
- Confusion.
- Depression.
- Being less alert.

Liver and kidneys

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

- Yellowing of your skin or the white of your eyes (jaundice).

Stomach and gut

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

Heart and circulation

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

Eyes and ears

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

Skin

- Skin rashes.

Sexual

- A higher or lower interest in sex.

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:

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

Less common withdrawal symptoms include:

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

Injury

- Patients taking benzodiazepine medicines are at risk of falling and breaking bones. This risk is increased in older people and those taking other sedatives (including alcohol).

If any of the side effects become serious or troublesome, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly (see details below).

Ireland

HPRa Pharmacovigilance, Earlsfort Terrace, IRL – Dublin 2, Tel: +353 1 6764971, Fax: +353 1 6762517, Website: www.hpra.ie, e-mail: medsafety@hpra.ie

Malta

ADR Reporting

Website: www.medicinesauthority.gov.mt/adrportal

By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Valium

- Keep out of the sight and reach of children.
- Do not use this medicine after the expiry date which is printed on the carton and blister foil after (EXP). The expiry date refers to the last day of that month.
- Valium tablets do not require any special storage conditions.
- Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment. Only keep Valium tablets if your doctor tells you to.

6. Contents of the pack and other information

What Valium contains

The active substance in Valium is diazepam. Each Valium 5 mg tablet contains 5 mg (milligrams) of diazepam.

The other ingredients in Valium tablets are lactose monohydrate, maize starch, magnesium stearate and yellow iron oxide (E172).

What Valium looks like and contents of the pack

- Valium 5 mg Tablets are round, pale yellow in colour, marked Roche 5 on one side and have a break line on the other.
- Valium tablets have a break line so that they can easily be broken into halves.
- Valium tablets are supplied in blister packs which contain 100 tablets.

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