

DIAZEPAM 2MG, 5MG & 10MG TABLETS

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.
- This medicine contains diazepam, which can cause dependence, tolerance and addiction. You can get withdrawal symptoms if you stop taking it or reduce the dose suddenly.
- If this medicine is being used for the treatment of epilepsy you must continue to take this medicine as instructed by your doctor.

What is in this leaflet:

1. What is Diazepam and what it is used for
2. What you need to know before you take Diazepam
3. How to take Diazepam Tablets
4. Possible side effects
5. How to store Diazepam Tablets
6. Contents of the pack and other information

1. What is Diazepam and what it is used for

Diazepam belongs to a group of medicines called benzodiazepines. Diazepam helps in the treatment of anxiety, muscle spasms and convulsions (fits).

Benzodiazepines can cause dependence, tolerance and addiction, and you may get withdrawal symptoms if you stop taking it or reduce the dose suddenly. Your prescriber should have explained how long you will be taking it for and, when it is appropriate to stop, how to do this safely. When your treatment is stopped, it is usually done gradually over a period which is specific to you and may occur over a period of weeks to months.

If this medicine is being used for the treatment of epilepsy you must continue to take it as prescribed by your doctor.

Diazepam tablets are used to treat a number of conditions, including:

In adults

- short term relief (2-4 weeks only) of severe anxiety (an emotional state where you may sweat, tremble, feel anxious and have a fast heart beat) occurring alone or with insomnia (trouble sleeping) or mental health problems
- short term treatment of conditions where anxiety may cause tension headaches or migraine attacks
- helping muscle relax and for muscle spasm and cerebral palsy (a condition affecting the brain which causes movement problems and rigidity or stiffness)
- epilepsy (when taken with other medicines)
- patients with the symptoms of acute alcohol withdrawal
- can take before operation to help with relaxation and to cause sleepiness
- As an adjunct to the control of muscle spasm in tetanus.

In children

- helping to treat tension and irritability caused by cerebral spasticity
- helping to treat muscle spasm caused by tetanus (when taken with other medicines)
- can use before operation but only with extreme caution (see section 2)

2. What you need to know before you take Diazepam

Do not take diazepam tablets and tell your doctor if you:

- are **allergic** (hypersensitive) to diazepam or to other benzodiazepine medicines or to any of the other ingredients in your tablets (see section 6)
- have severe breathing (respiratory depression) problems
- are taking anti-psychotics, antidepressants, hypnotics, antihistamines
- suffer from phobic (fear that is out of proportion to the situation that causes it and cannot be explained away) or obsessional state
- suffer from chronic psychosis (an illness of the brain in which thoughts are disordered and reality distortions occur, like hallucinations and delusions)
- have acute pulmonary insufficiency (a condition that affects the heart)
- have '**myasthenia gravis**' (very weak or tired muscles)
- suffer from '**sleep apnoea**' (breathing problem when you are asleep)
- have serious **liver** problems
- suffer from a condition called '**porphyria**' (inherited condition causing skin blisters, abdominal pain and brain or nervous system disorder)
- have suffered from **depression** before
- planning a **pregnancy** or are **pregnant** (see below *pregnancy and breast feeding*)

Warnings and precautions

Talk to your doctor or pharmacist before taking this tablet if you

- have a history of **alcoholism** or **drug abuse**
- have problems with your **lungs, heart, and liver** or have **severe kidney failure**
- have suffered a loss of **bereavement**
- have **suicidal feelings**. Since diazepam may increase the suicidal effects
- have **low blood levels** of a protein called albumin
- have **personality disorder**
- have poor blood supply to the brain (atherosclerosis)
- are **elderly** (risk of confusion or clumsiness causing you to fall or injure yourself)
- suffer from eye problem called **glaucoma**
- **smoke**
- are **children** (extreme caution required as the effects and timing of action/response of diazepam used before operation in children may be unreliable and/or paradoxical)
- are or have ever been addicted to opioids, alcohol, prescription medicines, or illegal drugs, or if you have ever had a history of struggling to control your alcohol or drug intake.
- have previously suffered from withdrawal symptoms such as agitation, anxiety, shaking or sweating, when you have stopped taking alcohol or drugs.
- feel you need to take more of <product name> to get the same level of symptom control, this may mean you are developing tolerance to the effects of this medicine or

are becoming addicted to it. Speak to your prescriber who will discuss your treatment and may change your dose or switch you to an alternative medication.

Taking this medicine regularly, particularly for a long time, can lead to physical dependence and addiction. Your prescriber should have explained how long you will be taking it for and, when it is appropriate to stop, how to do this safely. When your treatment is stopped, it is usually done gradually over a period which is specific to you and may occur over a period of weeks to months.

Physical dependence and addiction can cause withdrawal symptoms when you stop taking this medicine. Withdrawal symptoms can include:

- Benzodiazepines: headaches, muscle pain, anxiety, tension, depression, restlessness, sweating, confusion or irritability. Do not stop taking your tablets suddenly. This could lead to more serious symptoms such as loss of the sense of reality, feeling unreal or detached from life, and unable to feel emotion. Some patients have also experienced numbness or tingling of the arms or legs, tinnitus (ringing sounds in the ears), oversensitivity to light, sound and touch, uncontrolled or overactive movements, twitching, shaking, feeling sick, being sick, stomach upsets or stomach pain, loss of appetite, agitation, abnormally fast heartbeats, panic attacks, dizziness or feeling that you are about to fall, memory loss, hallucinations, feeling stiff and unable to move easily, feeling very warm, convulsions (sudden uncontrolled shaking or jerking of the body).

Your prescriber will discuss with you how to gradually reduce your dose before stopping the medicine. It is important that you do not stop taking the medicine suddenly as you will be more likely to experience withdrawal symptoms. Your prescriber will ensure that your plan for stopping treatment is tailored to you and can be adapted according to your needs and experience of any withdrawal symptoms.

Benzodiazepines should only be used by those they are prescribed for. Do not give your medicine to anyone else. Taking higher doses or more frequent doses of benzodiazepines, may increase the risk of addiction. Overuse and misuse can lead to overdose and/or death.

Taking other medicines

Please **tell your doctor or pharmacist** if you are taking or have recently taken any other medicines, including medicines obtained without a prescription:

- **antidepressants** (eg fluvoxamine), **antipsychotics** (to treat mental problem eg zotepine), anxiolytics/sedatives (eg lorazepam), **antihistamines** (to treat allergies), **general anaesthetics**, **lofexidine** (to help relieve symptoms when you stop taking opioids), **nabilone** (to treat nausea and vomiting), **hypnotics** (to help you sleep), **alpha blockers** or **moxonidine** (to lower high blood pressure), **muscle relaxants** (eg baclofen, tizanidine). Taking these medicines with diazepam could make you very sleepy
- some **strong pain killers** may increase sedative effect and make you very sleepy
- **disulfiram** (to treat alcohol addiction) could make you very sleepy
- **medicine for epilepsy** eg: phenobarbital, phenytoin, carbamazepine, or sodium valproate. Taking these medicines with diazepam could make you very sleepy
- **cimetidine** or **omeprazole** (for ulcers), **oestrogen-containing contraceptives**, **erythromycin** (an antibiotic), **antifungal** (fluconazole, voriconazole) or **isoniazid** (to treat tuberculosis) as these can cause diazepam to be removed from the body more slowly
- **rifampicin** (to treat infections) or **theophylline** (to treat asthma) as this can cause diazepam to be removed from the body more quickly than usual
- **amprenavir** or **ritonavir** (antivirals) as these can make you feel sleepy for longer or cause breathing difficulties
- **medicines to lower high blood pressure, diuretics** (water tablets), **nitrates** (for heart conditions) as these may lower your blood pressure too much
- **levodopa** (to treat Parkinson's Disease)
- **cisapride** (to treat gastric reflux)
- **antacids** (reduces stomach acid) may slow down absorption of diazepam in the body

Taking Diazepam tablets with food, drink and alcohol

- **Do not** drink alcohol while you are taking Diazepam tablets. Alcohol may increase the sedative effects of Diazepam tablets and make you very sleepy.
- Grapefruit juice may increase the amount of diazepam in your blood. If you are elderly, suffer from cirrhosis or any of the conditions listed in section 2, this could possibly increase the sedative effects of diazepam tablets and you should speak your doctor or pharmacist.
- Drinks containing caffeine may reduce the effects of diazepam.

Pregnancy and breast feeding

You should not take diazepam tablets if you are pregnant, planning to become pregnant or are breast feeding. If you take diazepam tablets in late pregnancy or during labour your baby might have a low body temperature, floppiness and breathing difficulties. If taken regularly during late pregnancy, your baby may develop withdrawal symptoms. Ask your doctor or pharmacist for advice before taking any medicine.

Driving and using machines

You should not drive, operate machinery or take part in such activities where, if affected, you could put yourself or others at risk as these tablets can make you sleepy, forgetful; have poor co-ordination along with other side effects that can affect everyday activities (see possible side effects).

Diazepam tablet contains lactose

Diazepam tablets contain lactose (a type of sugar). If you have been told that you have intolerance to some sugars contact your doctor before taking this medicine.

3. How to take Diazepam

Always take diazepam tablets exactly as your doctor has told you. **You should not take diazepam tablets for longer than 4 weeks.** Check with your doctor or pharmacist if you are not sure.

Your prescriber should have discussed with you how long the course of tablets will last. They will arrange a plan for stopping treatment. This will outline how to gradually reduce the dose and stop taking the medicine. Your prescriber will ensure that your plan for stopping treatment is tailored to you and can be adapted according to your needs and experience of any withdrawal symptoms.

Swallow the tablets **whole, with a glass of water.**

Doses



Adults

- **Anxiety state:** Starting dose of 2mg three times daily. Usual dose 2-5mg three times daily. If your symptoms are severe you may be given up to 30mg daily in divided doses.
- **Trouble sleeping associated with insomnia:** 5-15mg before retiring. Do not take more than the maximum dose. Allow 7 to 8 hours of uninterrupted sleep to avoid anterograde amnesia (partial or complete inability to recall the recent past)
- **Cerebral Palsy/Spasticity:** 2-60mg daily in divided doses (maximum – 60mg daily).
- **To help with alcohol withdrawal symptoms:** 5-20mg, repeated if necessary in 2-4 hours.
- **Muscle spasm:** 2-15mg in divided doses. (maximum – 15mg daily)
- **Muscle spasm in tetanus:** 3-10mg/kg daily by nasogastric tube. Dose is dependent on the symptoms, your doctor will decide the correct dosage.
- **Epilepsy:** 2-60mg daily in divided doses.
- **Pre-medication:** 5-20mg before the procedure.

Children

- **For tension and irritability in cerebral spasticity: Child 5-12 years:** initially 5mg twice a day
Adolescent 12 to 18 years: initially 10mg twice daily
Maximum 40 mg daily in divided doses
- **Muscle spasm in tetanus: children/ adolescents-** 3-10mg/kg daily by nasogastric tube. Dose is dependent on the symptoms, your doctor will decide the correct dosage.
- **Pre medication:** use with extreme caution (increase risk of inappropriate response-see section 2) 2-10mg before the procedure.

Elderly or debilitated patients

- Doses should not exceed half the adult dose. Treatment should always be tapered off gradually (increased sensitivity to CNS effect)
- Patients with liver or kidney problems may also be given a lower dose.
- Patients who have taken benzodiazepines for prolonged time may require a longer period of dosage reduction and specialist help may be appropriate.

If you take more Diazepam tablets than you should

If you (or someone else) swallow a lot of tablets at the same time, or you think a child may have swallowed any, contact your nearest hospital immediately. Signs of overdose include clumsiness and loss of coordination, feeling sleepy or deep sleep, speech problems, irregular or slow heartbeat, uncontrolled eye movement, muscle weakness or paradoxical excitation. An extreme overdose may lead to coma (unrousable unconsciousness), reflex problems and breathing difficulties.

If you forget to take Diazepam tablets

If you forget to take your medicine for anxiety, you should take it as soon as you remember if it is less than 3 hours since your usual time. If more than 3 hours have passed, then just continue taking your next dose; do not try to catch up by doubling up the dosage.

If you stop taking Diazepam tablets

Do not suddenly stop taking this medicine. If you want to stop taking this medicine, discuss this with your prescriber first. They will tell you how to do this, usually by reducing the dose gradually so that any unpleasant withdrawal effects are kept to a minimum. This may occur over a period of weeks to months. Your prescriber will ensure that your plan for stopping treatment is tailored to you and can be adapted according to your needs and experience of any withdrawal symptoms.

Withdrawal symptoms such as:

- Benzodiazepines: headaches, muscle pain, anxiety, tension, depression, restlessness, sweating, confusion or irritability. Do not stop taking your tablets suddenly. This could lead to more serious symptoms such as loss of the sense of reality, feeling unreal or detached from life, and unable to feel emotion. Some patients have also experienced numbness or tingling of the arms or legs, tinnitus (ringing sounds in the ears), oversensitivity to light, sound and touch, uncontrolled or overactive movements, twitching, shaking, feeling sick, being sick, stomach upsets or stomach pain, loss of appetite, agitation, abnormally fast heartbeats, panic attacks, dizziness or feeling that you are about to fall, memory loss, hallucinations, feeling stiff and unable to move easily, feeling very warm, convulsions (sudden uncontrolled shaking or jerking of the body).
- Do not stop taking your medicine without telling your doctor as he may wish to gradually reduce the number of tablets you take before stopping them completely. If you stop taking diazepam tablets suddenly, you may experience unpleasant side effect including depression, nervousness, irritability, sweating, quick or irregular heartbeat, muscle spasm, shaking, loss of appetite, feeling or being sick, stomach cramps or diarrhoea. If you have been taking a high dose, you may occasionally experience confusion or unusual behaviour. Patients at risk of convulsions may be more susceptible to suffering fits on withdrawal.
- Treatment should be gradually withdrawn otherwise the symptoms you are being treated for may return more intensely than before (rebound insomnia and anxiety). The risk of this happening is greater when you stop taking Diazepam suddenly. You may also experience mood changes, anxiety, restlessness or change in sleep patterns. If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them. If you experience any of the following serious side effects, tell your doctor **IMMEDIATELY**

Symptoms of an allergic reaction e.g. itchy skin, swelling of the face, lips, tongue or throat, or difficulty breathing or swallowing.

Tell your doctor if you notice any of the following side effects or notice any other effects not listed:

- drowsiness, tiredness, reduced alertness and muscle weakness are the most common side effects
- sedation, slurred speech, dizziness, light-headedness, unsteadiness or clumsiness and loss of co-ordination
- confusion, memory loss (which may be experienced several hours after taking diazepam. If possible, to reduce the risk allow 7 to 8 hours of uninterrupted sleep after taking), seeing or sensing things that are not there, inappropriate behaviour, difficulty in concentration, agitation/irritability, restlessness, experiencing rage, excitement,

nightmares, numbed emotions, depression with suicidal tendencies, headache, 'spinning' sensation

- blood disorders (you may develop sore throats, nose bleeds or infections) of the skin or whites of the eyes (jaundice), increased levels of liver enzymes in the blood
- changes in sex drive, enlargement of breasts in men
- visual disturbances, blurred or double vision
- low blood pressure
- stomach upsets, dry mouth, nausea, vomiting, constipation
- muscle spasms/shaking or weakness, breathing difficulties
- incontinence or difficulty passing urine, increase in amount of saliva
- you feel you are abusing or becoming dependant on this product
- dependence and addiction (see section "How do I know if I am tolerant or addicted?").

Withdrawal symptoms: see section 3, 'if you stop taking Diazepam tablets'.

Drug Withdrawal

When you stop taking diazepam tablets, you may experience drug withdrawal symptoms, which include:

- Benzodiazepines: headaches, muscle pain, anxiety, tension sweating, confusion or irritability. Do not stop taking your tablets suddenly. This could lead to more serious symptoms such as loss of the sense of reality, feeling unreal or detached from life, and unable to feel emotion. Some patients have also experienced numbness or tingling of the arms or legs, tinnitus (ringing sounds in the ears), oversensitivity to light, sound and touch, uncontrolled or overactive movements, twitching, shaking, feeling sick, being sick, stomach upsets o appetite, agitation, abnormally fast heartbeats, panic attacks, dizziness or feeling that you are about to fall, memory loss, hallucinations, feeling stiff and unable to move easily, feeling very warm, convulsions (sudden uncontrolled shaking or jerking of the body).

How do I know if I am tolerant or addicted?

If you notice any of the following signs whilst taking diazepam tablets, it could be a sign that you have become addicted.

- You may feel the need to keep taking the medication for longer than your doctor recommended
- You feel you need to use more than the recommended dose
- You are using the medicine for reasons other than prescribed
- When you stop taking the medicine you feel unwell, and you feel better once taking the medicine again

If you notice any of these signs, it is important you talk to your prescriber.

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 via the Yellow Card Scheme at: www.mhra.gov.uk/yellowcard

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

5. How to store Diazepam

- Do not use this medicine after the expiry date stated on the label/carton/ expiry date refers to the last day of that month.
- Store in cool dry place. Protect from bright light.
- Store in the original container. Keep the container tightly closed.

Keep all the medicines out of the sight and reach of children

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.

6. Contents of the pack and other information

What Diazepam 2mg tablets contain:

- **The active ingredient is** 2mg of diazepam.
- **The other ingredients are** lactose, maize starch, magnesium stearate, colloidal silicon dioxide and sodium starch glycolate.

What Diazepam 5mg tablets contain:

- **The active ingredient is** 5mg of diazepam.
- **The other ingredients are** lactose, maize starch, magnesium stearate, colloidal silicon dioxide, sodium starch glycolate and Tartrazine Lake.

What Diazepam 10mg tablets contain:

- **The active ingredient is** 10mg of diazepam.
- **The other ingredients are** lactose, maize starch magnesium stearate, colloidal silicon dioxide, sodium starch glycolate and aluminium lake patent blue V.

See end of section 2 for further information on lactose

What Diazepam tablets look like and contents of the pack:

- **Diazepam 2mg tablets** are white, flat, circular tablets with a bevelled edge and breakline. Embossed 'D/2' on one face, 'PV' on the other.
- **Diazepam 5mg tablets** are yellow, flat, circular tablets breakline. Embossed 'D/5' on one face, 'PV' on the other.
- **Diazepam 10mg tablets** are blue, flat, circular tablets with a bevelled edge and breakline. Embossed 'D/10' on one face, 'PV' on the other.

Pack sizes: Diazepam 2mg, 5mg & 10mg tablets are available in the pack sizes of 28, 30, 50, 56, 100, 250, 500 and 1000 tablets. Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacture:

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