

DIAZEPAM 2 mg, 5 mg and 10 mg TABLETS

Package leaflet: Information for the patient user

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

1 What Diazepam is and what it is used for

Diazepam Tablets belong to a group of drugs called benzodiazepines which promote sleep and relieves anxiety by altering brain activity concerned with emotion.

Diazepam is used:

- for the short term (2 - 4 weeks) relief of severe anxiety
- to relax muscles
- for the short term relief of difficulty in sleeping (when it is severe and causing distress)
- to relax or sedate people undergoing certain uncomfortable medical procedures.

2 What you need to know before you take Diazepam

DO NOT take Diazepam if you:

- are **allergic** (hypersensitive) to diazepam or benzodiazepines, or any of the other ingredients of this medicine
- have long-term or **severe liver problems**
- suffer from **severe breathing problems**
- suffer from **sleep apnoea** (difficulty breathing while asleep)
- suffer from **myasthenia gravis** (a disorder where muscles become weak and tire easily)
- suffer from **mental illness**, such as phobias, or obsessions
- suffer from depression (with or without anxiety) or hyperactivity
- have **porphyria** (an inherited condition causing skin blisters, abdominal pain and brain or nervous system disorders)
- suffer from **hyperkinesia** (a state of overactive restlessness)
- planning a **pregnancy** or are **pregnant** (see below Pregnancy and breast-feeding).

Diazepam should NOT be taken on its own to treat depression or anxiety associated with depression.

Warnings and precautions

Talk to your doctor or pharmacist before taking Diazepam if you:

- have suffered a loss or bereavement
- have lung problems
- have liver problems
- suffer from personality disorders
- have had problems with alcohol or drug abuse
- have problems with your **heart and lungs** or have **severe kidney failure**
- have **low blood levels** of a protein called albumin
- have a poor blood supply to the brain (**arteriosclerosis**)
- are **elderly** (risk of confusion or clumsiness causing you to fall or injure yourself)
- **smoke**.

Other important things to remember when taking Diazepam:

- **Dependence:** When taking this medicine there is a risk of dependence (a need to keep taking the medicine). The risk increases with the dose and length of treatment period. The risk is greater if you have ever had a history of alcohol or drug abuse, or suffer from a personality disorder.
- **Withdrawal:** When stopping this medicine you may experience **withdrawal effects and withdrawal symptoms** occur with Diazepam even when normal doses are given for short periods of time (see section 3, **If you stop taking Diazepam**). Treatment should be gradually withdrawn.
- **Tolerance:** if after a few weeks you notice that the tablets are not working as well as they did when first starting treatment, you should speak to your doctor.
- **Behavioural effects** may occur while taking Diazepam (see section 4, **Possible side effects**)
- To reduce the risk of amnesia (**loss of memory**), you should make sure that you are able to have an uninterrupted sleep of at least 7 hours
- Tell the hospital or dentist you are taking Diazepam if you are to have an operation requiring an anaesthetic.

Other medicines and Diazepam

Concomitant use of Diazepam 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.

However if your doctor does prescribe Diazepam together with opioids the dose and duration of concomitant treatment should be limited by your doctor.

Please tell your doctor about all opioid medicines you are taking, and follow your doctor's dose recommendation closely. It could be helpful to inform

friends or relatives to be aware of the signs and symptoms stated above. Contact your doctor when experiencing such symptoms.

Avoid Diazepam in combination with:

- sodium oxybate (used to prevent attacks of cataplexy (episodes of muscle weakness that begin suddenly and last for a short time) in patients who have narcolepsy (a sleep disorder that may cause extreme sleepiness, sudden uncontrollable urge to sleep during daily activities, and cataplexy)).
- zidovudine (HIV/AIDS drug).

Tell your doctor or pharmacist if you are taking, have recently taken or might take any of the following:

- **antidepressants** e.g. amitriptyline, fluvoxamine or fluoxetine, **antipsychotics** e.g. chlorpromazine, haloperidol (to treat mental problems e.g. zotepine), antihistamines with a sedative effect (for allergies) e.g. chlorphenamine, promethazine, , **general anaesthetics**, **lofexidine** (to help relieve symptoms when you stop taking opioids), **nabilone** (to treat nausea and vomiting), **hypnotics** e.g. temazepam, zopiclone (to help you sleep), **alpha blockers** or **moxonidine** (to lower high blood pressure), **muscle relaxants** (e.g. baclofen, tizanidine), anxiolytics/sedatives e.g. lorazepam, buspirone. Taking these medicines with diazepam could make you very sleepy.
- some **strong pain killers** (e.g. codeine, co-proxamol) may give you a heightened sense of wellbeing when taken with diazepam, which can increase your desire to continue taking these medicines (dependency) or can make you very sleepy
- lofexidine (used for the management of withdrawal symptoms in patients undergoing heroin or opiate detox), nabilone (used for treatment of feeling and being sick), **disulfiram** (to treat alcohol addiction), baclofen and tizanidine (used to relieve muscle spasms). Taking this medicine with diazepam could make you very sleepy and can cause diazepam to be removed from the body more slowly than usual.
- **medicines for epilepsy** e.g. phenobarbital, phenytoin, carbamazepine, or sodium valproate, (diazepam can affect the blood levels of these medicines)
- **cimetidine** or **omeprazole** or esomeprazole (for ulcers), **oestrogen-containing contraceptives**, **erythromycin** (an antibiotic), antifungals (itraconazole, ketoconazole, fluconazole, voriconazole) or **isoniazid** (to treat tuberculosis) as these can cause diazepam to be removed from the body more slowly than usual
- **rifampicin** (to treat infections) or theophylline (to treat asthma) as this can cause diazepam to be removed from the body more quickly than usual
- **amrenavir** or **ritonavir** (antivirals) as these can make you feel sleepy for longer or cause difficulty breathing
- medicines to lower high blood pressure (e.g. hydralazine, minoxidil, sodium nitroprusside), diuretics (water tablets), nitrates (for heart conditions), ACE inhibitors (used to treat high blood pressure, e.g. perindopril, captopril), alpha-blockers (used to treat high blood pressure, e.g. alfuzosin, prazosin), angiotensin-II receptor antagonists (used to treat high blood pressure, e.g. valsartan), calcium channel blockers (used to treat high blood pressure, e.g. amlodipine), adrenergic neurone blockers (used to treat high blood pressure, e.g. reserpine), beta-blockers (used to treat high blood pressure, e.g. bisoprolol) as these could lower your blood pressure too much
- **levodopa** (to treat Parkinson's Disease) as diazepam may cause levodopa to not work so well
- **antacids** (reduces stomach acid) may slow down absorption of diazepam in the body
- **cisapride** (used to treat gastric reflux)

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines, including medicines obtained without a prescription.

Diazepam with food and drink

- **DO NOT drink** alcohol while taking these tablets, as it may increase the sedative effect of the drug.
- 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 to your doctor or pharmacist.
- Drinks containing caffeine may reduce the effects of diazepam.

Pregnancy and breast-feeding

You **should not** take Diazepam if you are pregnant, planning to become pregnant or are 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.

If your doctor has decided that you should receive this medicine during late pregnancy or during labour, your baby might have a low body temperature, floppiness, and breathing and feeding difficulties. If this medicine is taken regularly in late pregnancy, your baby may develop withdrawal symptoms. Ask your doctor or pharmacist for advice before taking any medicine.

Driving and using machines

- Your tablets may make you confused, forgetful, drowsy, unsteady or affect your co-ordination along with other side effects that can affect everyday activities (see Possible side effects). These effects may be increased if you have not had enough sleep. **DO NOT** drive or operate machinery if you are affected.

The medicine can affect your ability to drive as it may make you sleepy or dizzy.

- Do not drive while taking this medicine until you know how it affects you.
- It is an offence to drive if this medicine affects your ability to drive.

However, you would not be committing an offence if:

- The medicine has been prescribed to treat a medical or dental problem and
- You have taken it according to the instructions given by the prescriber or in the information provided with the medicine and
- It was not affecting your ability to drive safely

Talk to your doctor or pharmacist if you are not sure whether it is safe for you to drive while taking this medicine.

Diazepam contains lactose and E110 (sunset yellow)

- Patients who are intolerant to lactose should note that Diazepam Tablets contain a small amount of lactose. If your doctor has told you that you have an intolerance to some sugars, contact your doctor before taking this medicine.
- The 5 mg tablet contains **E110 (sunset yellow)**, which may cause allergic reactions.

3 How to take Diazepam

Always take this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure. You should continue to take these tablets for as long as your doctor tells you to. The tablets should be swallowed with a drink of water.

Your doctor will decide on the correct dosage; the recommended dose is:

Anxiety:

- **Adults:** 2 mg three times daily. If your symptoms are severe you may be given 15 – 30 mg daily taken in divided doses.

Muscle spasm:

- **Adults:** 2 - 60 mg daily taken in divided doses.
- **Children:** 2 - 40 mg daily taken in divided doses. For both adults and children the dose is dependent on the symptoms, your doctor will decide on the correct dosage.

Trouble in sleeping associated with anxiety:

- **Adults:** 5 - 15 mg before going to bed. Do not take more than the maximum dose.

Pre-medication:

- **Adults:** 5 - 20 mg
- **Children:** 2 - 10 mg

Use in children:

Your doctor will want to carefully assess children who are given Diazepam and keep the length of treatment as short as possible.

Elderly and Debilitated (very frail) patients:

Normally the starting dose is half of the ordinary adult dose. If you are elderly or frail you are likely to be more sensitive to the effects of Diazepam, such as confusion, and your doctor will give you much lower doses. The dose should not be more than half the adult dose.

Patients with liver problems:

Your doctor may prescribe a lower dose.

Long-term use of Diazepam is not recommended.

Treatment should not normally last more than 4 weeks for sleeping problems or 2 – 3 months for anxiety.

You may become tolerant to the effects of Diazepam after you have been taking it for a few weeks. If you notice that the tablets are not working as well as they did when you first started taking them, you should go and see your doctor as an adjustment to your dosage may be required.

If you take more Diazepam than you should

If you (or someone else) swallow a lot of the tablets all together, or if you think a child has swallowed any of the tablets, contact your nearest hospital casualty department or your doctor immediately.

Signs of an overdose include clumsiness and loss of coordination, feeling sleepy or deep sleep, speech problems or slurred speech, irregular or slow heartbeat, difficulty in controlling movements, uncontrolled eye movement, muscle weakness or excitement, low blood pressure. An extreme overdose may lead to coma (unrousable unconsciousness), reflex problems and breathing difficulties.

Please take this leaflet, any remaining tablets, and the container with you to the hospital or doctor so that they know which tablets were consumed.

If you forget to take Diazepam

If you forget to take a tablet, take one as soon as you remember, unless it is nearly time to take the next one. DO NOT take a double dose to make up for a forgotten tablet.

If you stop taking Diazepam

DO NOT stop taking your tablets suddenly, or without your doctor telling you, as you may suffer from **withdrawal effects**.

If your doctor decides to stop your tablets, they will reduce the dose gradually to minimise any withdrawal effects, which may include:

- headache, muscle pain, tension
- severe anxiety, confusion, restlessness, depression, nervousness, sweating, quick or irregular heartbeat, muscle spasms, shaking, loss of appetite, feeling or being sick, stomach cramps or diarrhoea and irritability.
- **in severe cases** of withdrawal you may experience a feeling of things being unreal, a feeling of detachment from your surroundings, numbness and tingling in the hands and feet, sounds seeming to be louder than usual and which can sometimes be painful if the sound is loud, sensitivity to light or touch, hallucinations and fits
- 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 changes in sleep patterns. Even when you stop taking Diazepam gradually, you may feel anxious, depressed

and restless and have difficulty sleeping. You may also experience sweating and diarrhoea. If this happens go to your doctor for advice.

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.

Stop taking the tablets and tell your doctor immediately or go to the casualty department at your nearest hospital if the following happens:

- an allergic reaction (swelling of the lips, face or neck leading to severe difficulty in breathing; skin rash or hives).

This is a very serious but rare side effect. You may need urgent medical attention or hospitalisation.

Tell your doctor immediately if you suffer from:

- behavioural changes such as restlessness, agitation, irritability, aggressiveness, delusions, rages, nightmares, seeing or sensing things that are not there, psychiatric disorders and inappropriate behaviour, as your treatment may be stopped.

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

- drowsiness, sedation, tiredness, slurred speech, light-headedness, unsteadiness or clumsiness and loss of co-ordination (you may notice these even after a single dose and this may continue into the following day)
- confusion (particularly in the elderly), 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), poor concentration, excitement, numbed emotions, reduced alertness depression with suicidal tendencies, headache, 'spinning' sensation, difficulty sleeping, anxiety
- blood disorders (you may develop sore throats, nose bleeds or infections) changes in sex drive, low blood pressure
- muscle spasms/shaking or weakness, difficulty in controlling movements, breathing difficulties
- incontinence or problems passing urine
- you feel you are abusing or becoming dependant on this product
- visual disturbances, blurred or double vision
- nausea, vomiting, stomach problems, dry mouth, diarrhoea, constipation, the production of too much or too little saliva
- skin reactions.

Rarely, jaundice (characterised by the yellowing of the skin or the whites of the eyes) and very rarely increased levels of liver enzymes in the blood may occur.

Withdrawal effects are known to occur (see section 3, **If you stop taking Diazepam**)

Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist. 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 or search for MHRA Yellow Card in the Google Play or Apple App Store. By reporting side effects you can help provide more information on the safety of this medicine.

5 How to store Diazepam

Keep this medicine out of the sight and reach of children. Do not store above 25°C. Store in the original package in order to protect from light and moisture. Do not transfer them to another container.

Do not use this medicine after the expiry date which is stated on the carton. The expiry date refers to the last day of that month.

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 Tablets contain:

- The active substance is diazepam. Each tablet contains 2 mg, 5 mg, or 10 mg diazepam.
- The other ingredients are lactose monohydrate, powdered cellulose, maize starch, pregelatinised maize starch and magnesium stearate (E572). The 5 mg tablet also contains the colours quinoline yellow (E104) and sunset yellow (E110). The 10 mg tablet contains the colour indigo carmine (E132).

What Diazepam Tablets look like and contents of the pack:

- Diazepam Tablets 2 mg are white, flat, bevel edged tablets. They are engraved "Berk 2" with a breakline on reverse or "2" with a breakline on reverse.
- Diazepam Tablets 5 mg are yellow, flat, bevel edged tablets. They are engraved "Berk 5" with a breakline on reverse or "5" with a breakline on reverse.
- Diazepam Tablets 10 mg are blue, flat, bevel edged tablets. They are engraved "Berk 10" with a breakline on reverse or "10" with a breakline on reverse.

The tablets are available in pack sizes of 7, 10, 14, 21, 28, 30, 56, 60, 84, 90, 100, 110, 112, 120, 150, 160 or 168. Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder

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