

**Package leaflet: Information for the user****Diazepam 2mg, 5mg and 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, pharmacist or nurse.
- 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, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

**What is in this leaflet**

1. What Diazepam tablets are and what they are used for
2. What you need to know before you take Diazepam tablets
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 tablets are and what they are used for**

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

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

- short term relief (2-4 weeks only) of severe anxiety, which is an emotional state where you may sweat, tremble, feel anxious and have a fast heart beat and may occur alone or with insomnia (trouble sleeping) or mental health problems
- helping muscles 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 alcohol withdrawal.
- helping to relax nervous dental patients.

**In children**

- helping to treat tension and irritability caused by cerebral spasticity (a condition associated with a disease or trauma affecting the brain or spinal cord which causes weakness, un-coordinated movements, rigidity and stiffness)
- helping to treat muscle spasm caused by tetanus (when taken with other medicines)

Both adults and children can take Diazepam tablets before an operation to help with relaxation and to cause sleepiness.

This medicine should be used for as short a time as possible and should not be used for more than four weeks. If used for too long without a break, there is a risk of becoming dependent or of having problems when you stop taking it.

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.

**2. What you need to know before you take Diazepam tablets****Do not take** Diazepam tablets and **tell** your doctor if you

- are **allergic** (hypersensitive) to diazepam or to other benzodiazepine medicines or any of the other ingredients in your tablets (listed in section 6)
- **breathing problems**, which may be severe, including slow and/or shallow breathing
- suffer from **depression** (with or without anxiety) or hyperactivity
- have a **phobia** (a fear of a particular object or situation) or other mental illness
- have **myasthenia gravis** (a condition which causes muscles to weaken and tire easily)
- suffer from **sleep apnoea** (a sleep disorder where you have abnormal pauses in breathing during sleep)
- have **severe liver** disorders
- have **porphyria** (an inherited condition causing skin blisters, abdominal pain and brain or nervous system disorders)
- planning a **pregnancy** or are **pregnant** (see below *Pregnancy and breast-feeding*).

**Warnings and precautions****Talk to your doctor, pharmacist or nurse** before taking Diazepam tablets if you

- have a history of **alcoholism** or **drug abuse**
- have problems with your **heart and lungs** or have **severe kidney failure**
- have someone **close to you** that has recently died
- have **low blood levels** of a protein called albumin
- have a **personality disorder**
- have a poor blood supply to the brain (**arteriosclerosis**)
- are **elderly** (Diazepam tablets can cause confusion and have effects on muscles causing falls and injuries).
- have **breathing difficulties**
- **smoke**
- suffer from **depression**
- have **suicidal thoughts**
- have **epilepsy** or a history of **seizures**

**Other considerations**

- **Mental side effects** – contact your doctor if you experience side effects such as agitation hyperactivity, restlessness, aggressiveness, nightmares or hallucinations. These side effects are more likely to occur in children or the elderly.
- **Amnesia** (total or partial memory loss) – you could experience amnesia when taking this medicine. Amnesia is more likely to occur when taking high doses of diazepam.
- **Dependence** - when taking this medicine there is a risk of dependence, which increases with the dose and duration of treatment and also in patients with a history of alcoholism and drug abuse. Therefore, you should take Diazepam tablets for a short period of time as possible.
- **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.
- **Withdrawal** – treatment should be gradually withdrawn. Withdrawal symptoms occur with Diazepam tablets even when normal doses are given for short periods of time. See Section 3, ‘**If you stop taking Diazepam tablets.**’

**Other medicines and Diazepam tablets**

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

- **sodium oxybate** (used to prevent episodes of sudden onset of sleep (narcolepsy) with muscle weakness)

- **Antidepressants** (e.g. fluvoxamine, fluoxetine)
- **Antipsychotics** such as clozapine (to treat mental problems)
- **Antihistamines** (to treat allergies)
- **General anaesthetics**
- **Sedatives** (used to give calming effects)
- **Hypnotics** (to help you sleep)
- **Erythromycin** (an antibiotic)
- **Muscle relaxants** (e.g. suxamethonium, tubocurarin)
- Some **strong pain killers** such as **morphine** (opioids) may give you a heightened sense of well being when taken with diazepam, which can increase your desire to continue taking these medicines (dependency) or can make you very sleepy.
- Barbiturates such as **phenobarbital** (to treat epilepsy and mental disorders)
- **Medicines to lower high blood pressure, diuretics** (water tablets), **nitrates** (for heart conditions) as these could lower your blood pressure too much.
- **Antacids** (reduces stomach acid) may slow down absorption of diazepam in the body.

Taking these medicines with diazepam could affect your mental status, make you very sleepy and suppress your breathing and blood pressure.

- **Disulfiram** (to treat alcohol addiction). 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 and carbamazepine, sodium valproate, (diazepam can affect the blood levels of these medicines). Diazepam can furthermore affect how phenytoin works.
  - Hypericum perforatum (perforate St. John’s wort, a herbal remedy)
  - **Theophylline** (to treat asthma and other breathing disorders), as it can weaken the effect of diazepam. As this can cause diazepam to be removed from the body more quickly than usual.
  - **Cimetidine, omeprazole or esomeprazole** (stomach acid reducing medicines), as these can cause diazepam to be removed from the body more slowly than usual.
  - **Rifampicin**, to treat infections (an antibiotic) as this can cause diazepam to be removed from the body more quickly than usual. The effect of diazepam can be weakened.
  - **Amrenavir, atazanavir, ritonavir, delavirdine, efavirenz, indinavir, nelfinavir, zidovudine or saquinavir** (antivirals), **fluconazole, itraconazole, ketoconazole** or **voriconazole** (anti -fungal medicines) as these can cause diazepam to be removed from the body more slowly than usual and therefore increase the risk of side effects. As these can make you feel sleepy for longer or cause difficulty breathing.
  - **Isoniazid** (used to treat tuberculosis), as it can cause diazepam to be removed from the body more slowly than usual.
  - **Oral contraceptives**, as they can slow down the removal of diazepam from the body and increase its effect. Breakthrough bleeding can occur when taking diazepam and oral contraceptives together, but the contraceptive protection is not reduced.
  - **Cisapride** (used to treat stomach problems), as it can cause diazepam to be removed from the body more slowly than usual.
  - **Corticosteroids** (medicines used to treat inflammation in the body) as they can weaken the effect of diazepam.
  - **Levodopa** (used to treat Parkinson’s disease). Diazepam can reduce the effect of levodopa.
  - **Valproic acid** (used to treat epilepsy and mental disorders) as it can slow down the removal of diazepam from the body and increase its effect.
  - **Ketamine** (an anaesthetic) as diazepam increases the effect of ketamine.
  - **Lofexidine** (to help relieve symptoms when you stop taking opioids)
  - **Nabilone** (to treat nausea and vomiting)
  - **Alpha blockers, beta blockers** or **moxonidine** (to lower high blood pressure)
- Concomitant use of Diazepam tablets 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 tablets 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.

**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 to your doctor or pharmacist. Drinks containing caffeine may reduce the effects of diazepam.

**Pregnancy, breast-feeding and fertility**

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

You **should not** take Diazepam tablets if you are pregnant, planning to become pregnant or are breast feeding. If you take Diazepam tablets late in your pregnancy or during labour this may harm your baby. The baby may have a low temperature, be listless, have breathing problems or difficulty in feeding. If taken regularly during late pregnancy, your baby may develop withdrawal symptoms. If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

**Driving and using machines**

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

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 tablets contain lactose**

If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.

**3. How to take Diazepam tablets**

Always take this medicine exactly as your doctor or pharmacist 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.

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

**The recommended dose is:****Adults**

- Anxiety or mental health problems: 2 mg three times a day. Maximum dose per day is 30mg in divided doses, adjusted on an individual basis.
- To help you sleep: 5mg-15mg at bedtime.
- To help cerebral palsy or other spasticities: 2mg-60mg each day, in divided doses.

- To help control muscle spasm: 2mg-15mg each day, in divided doses.
- To help epilepsy: 2mg-60mg each day, in divided doses.
- To help with alcohol withdrawal symptoms: 5mg-20mg, which may be repeated after 2 to 4 hours if necessary.
- Before dental treatment: 5mg the night before treatment, 5mg on waking and 5mg two hours before the appointment.
- Before an operation: 5mg-20mg

#### Children and adolescents

For tension and irritability in cerebral spasticity: 2mg-40mg each day, in divided doses.

If your doctor has given your child Diazepam tablets to take before an operation, the usual dose is 2mg-10mg.

#### Elderly/Frail people

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

#### Kidney or liver impairment

If you have liver or kidney problems you may also be given a lower dose.

#### 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 casualty department or tell your doctor immediately. Signs of an overdose include clumsiness and loss of coordination, feeling sleepy or deep sleep, speech problems, irregular or slow heartbeat, uncontrolled eye movement, muscle weakness or excitement. An extreme overdose may lead to coma (unrousable unconsciousness), reflex problems and breathing difficulties.

#### If you forget to take Diazepam tablets

Do not take a double dose to make up for a forgotten dose. If you forget to take a dose take it as soon as you remember it and then take the next dose at the right time.

#### If you stop taking Diazepam tablets

This medicine should not be stopped suddenly; keep taking it until your doctor tells you how to reduce the dose slowly. If you stop taking Diazepam tablets suddenly, you may experience the following withdrawal effects:

- Depression
- Nervousness
- Irritability
- Difficulty in sleeping
- Sweating,
- Upset stomach/diarrhoea,
- Or symptoms you are being treated for can come back worse than before.

If you have been taking a high dose, you may occasionally experience confusion, convulsions or unusual behaviour. 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. These effects may occur even after taking low doses for a short period of time. If you stop taking these tablets suddenly after being treated with high doses of Diazepam tablets, you may experience confusion, hallucinations, shaking, faster heartbeat or fits. Withdrawal may also cause unusual behaviour including aggressive outbursts, excitement or depression with suicidal thoughts or actions.

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.

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

**Some side effects can be serious and may require immediate medical treatment:**

- **Uncommon: may affect up to 1 in 100 people**
- Respiratory depression (very slow and/or shallow breathing)

**Rare: may affect up to 1 in 1,000 people**

- Respiratory arrest (cessation of breathing)
- Unconsciousness
- Jaundice (yellowing of your skin or the white of your eyes)

**Very rare: may affect up to 1 in 10,000 people**

- Anaphylaxis (severe allergic reaction) with symptoms such as sudden wheezing, swelling of your lips, tongue and throat or body, rash, fainting or difficulties to swallow

**Other side effects:**

**Very common: may affect more than 1 in 10 people**

- Drowsiness

**Common: may affect up to 1 in 10 people**

- Fatigue
- Withdrawal symptoms (for possible symptoms please see *'If you stop taking Diazepam tablets'* in Section 3)
- Confusion
- Loss of coordination of muscle movements (ataxia) and other movement disorders, tremor

**Uncommon: may affect up to 1 in 100 people**

- Muscle weakness
- Memory loss
- Difficulty in concentrating
- Balance disorders
- Dizziness
- Headache
- Slurred speech
- Stomach and intestinal problems such as nausea, vomiting, constipation, diarrhoea
- Increased salivation
- Allergic skin reactions in the form of itching, skin redness and swelling and skin rash.

**Rare: may affect up to 1 in 1,000 people**

- Mental side effects such as excitation, agitation, restlessness, irritability, aggressiveness, memory loss, inappropriate behaviour, delusion, rages, psychoses, nightmares or hallucinations. May be or become serious. These side effects are more likely to occur in children or the elderly. Talk to your doctor.

- Decreased alertness
- Depression
- Emotional withdrawal
- Insomnia (problems sleeping)
- Heart problems such as slow heartbeat (bradycardia), heart failure and cessation of heartbeat (cardiac arrest).
- Low blood pressure, fainting (syncope)
- Increased mucus in the lungs
- Dry mouth
- Increased appetite
- Changes in certain liver enzymes as seen in blood tests
- Lack of ability to urinate, loss of bladder control (leakage of urine)
- Breast enlargement in men
- Impotence, changes in sexual drive (libido)
- Blood disorders (you may develop sore throats, nose bleeds or infections)

**Very rare: may affect up to 1 in 10,000 people**

- Low levels of white blood cells (leukopenia)
- Higher level of a certain enzyme in the blood (transaminase)

**Not known: frequency cannot be estimated from the available data**

- Blurred vision, double vision and involuntary eye movements (these side effects disappear after you have stopped taking diazepam)

Withdrawal symptoms: see Section 3, **'If you stop taking Diazepam tablets.'**

#### 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 Website: [www.mhra.gov.uk/yellowcard](http://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 tablets

- Keep this medicine out of the sight and reach of children.
- Store in a dry place below 25°C.
- Do not use this medicine after the expiry date which is stated on the label after EXP. 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 either 2mg, 5mg or 10mg of the active ingredient.
- The other ingredients are lactose, magnesium stearate, Starch, Microcrystalline cellulose and Colloidal Hydrated silica.
- The 5mg tablets also contain Yellow iron oxide.
- The 10mg tablets also contain Indigo carmine lake disperse 15009.

#### What Diazepam tablets look like and contents of the pack

- 2 mg: Flat white bevel edged tablet with breakline on one face and debossed "D2" on reverse.
- 5 mg: Pale yellow flat bevel edged tablet with breakline on one face and debossed "D5" on reverse.
- 10 mg: Light blue flat bevel edged tablet with breakline on one face and debossed "D10" on the reverse.
- The product is available in packs of 50, 500 and 1000 in securitainers. The container is made up of High Density Polypropylene body and Low Density Polyethylene cap.
- Not all pack sizes may be marketed.

#### Marketing Authorisation Holder and Manufacturer:

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**Diazepam Tablets 2mg; PL 17907/0448**

**Diazepam Tablets 5mg; PL 17907/0449**

**Diazepam Tablets 10mg; PL 17907/0450**

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