

## PACKAGE LEAFLET: INFORMATION FOR THE PATIENT

**DIAZEPAM** Tablets 2mg, 5mg and 10mg

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.

**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 is and what it is used for
2. What you need to know before you take Diazepam Tablets
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 Diazepam Tablets is and what it is used for**

This medicine has been prescribed for you for relief of anxiety.

It contains the Diazepam which belongs to a class of medicines called benzodiazepines which work by having a calming effect on various functions of the brain.

This medicine has been prescribed to you and should not be given to anyone else.

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 is used to treat a number of conditions including the following:

- short-term relief (2-4 weeks only) of severe anxiety (an emotional state where you may sweat, tremble, feel anxious and have a fast heartbeat); this may occur alone or with difficulty in sleeping or mental health problems
- severe insomnia (difficulty sleeping)
- helping muscle spasms relax and for muscle relax and cerebral palsy (a condition affecting the brain which causes movement problems and rigidity or stiffness) or tetanus
- symptoms of alcohol withdrawal
- with other medicines to treat epilepsy (fits)
- helping patients relax before surgery or dental procedures.

This medicine can also be used for children to help them relax before surgery, to control muscle spasms/twitching caused by tetanus and controlling tension and irritability in 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).

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 stopping 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 or you have a personality disorder.

**2. What you need to know before you take Diazepam Tablets****Do not take Diazepam Tablets if you:**

- are allergic (hypersensitive) to diazepam, or other benzodiazepine medicine, or any of the other ingredients of this medicine (listed in section 6)
- have difficulty in breathing or any kind of lung disease e.g. asthma
- suffer from phobias (a fear of a particular object or situation) or other mental illness
- suffer from myasthenia gravis (a condition which causes muscles to weaken and tire easily)
- suffer from severe liver disorders
- suffer from porphyria (an inherited condition causing skin blisters, abdominal pain and brain or nervous system disorders)
- suffer from sleep apnoea (sometimes stop breathing during sleep)
- suffer from depression (with or without anxiety) or hyperactivity
- are planning a pregnancy or are pregnant (see pregnancy and breast-feeding section).

**Warnings and precautions**

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

- have disease of the arteries, kidney or liver
- have breathing difficulties
- smoke
- have problems with your lungs and heart
- have severe kidney failure
- have depression or mental illness
- have a history of alcohol or drug abuse
- have hypoalbuminaemia (low levels of albumin in your blood which can cause swelling)
- are elderly (diazepam may make you confused or clumsy or affect muscles, causing you to fall or injure yourself)
- have a personality disorder
- have epilepsy or history of seizures
- have poor blood supply to the brain (arteriosclerosis)
- have suicidal thoughts
- have recently suffered a bereavement (someone close to you has died).
- 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 Diazepam Tablets 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.

**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 as short a 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.'

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: 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.

**Other medicines and Diazepam Tablets**

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines. 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
- 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.
- 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.
- *hypericum perforatum* (Perforate St John's wort, a herbal remedy)
- 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 and breast-feeding**

**Do not** take Diazepam if you are pregnant, might become pregnant or breast-feeding. If you and your doctor decide that you should take this medicine towards the end of 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. Also, if you take this medicine regularly during your pregnancy your baby may get withdrawal symptoms.

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.

Product:	Diazepam Tablets 2mg, 5mg, and 10mg
Item Code:	P3629T
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Colours Used	
	Process Black
	Keyline - does not print

**Driving and using machines**

The medicine can affect your ability to drive and operate machinery as it may make you sleepy, dizzy, forgetful or have poor co-ordination along with other side effects that can affect everyday activities (see Possible side effects). These effects may continue into the next day or several days after taking, even after a single dose.

- You should not drive, operate machinery or take part in such activities where, if affected, you could put yourself or others at risk.
- 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 instruction 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**

Your prescriber should have discussed with you how long the course of Diazepam 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.

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 not take Diazepam Tablets for longer than 4 weeks.**

The tablets should be swallowed with a drink of water.

This medicine can make you suffer memory loss several hours after taking it. Try to make sure you can have 7 to 8 hours of uninterrupted sleep each night whilst you are taking this medicine.

The recommended dose is:

**Adults:**

- **Relief of severe anxiety and other mental health problems:** Take 5-30mg daily in divided doses.
- **Insomnia associated with anxiety:** Take 5-15mg at bedtime.
- **Cerebral palsy or other spasticities:** Take 5-60mg daily in divided doses.
- **Muscle spasm:** Take 5-15mg daily in divided doses.
- **As additional treatment of some forms of epilepsy:** 2-60mg daily in divided doses.
- **Before surgery:** 5-20mg.
- **Treatment of withdrawal symptoms of alcohol:** Take 5-20mg, repeated if necessary in 2-4 hours.
- **Before dental procedures:** 5mg the night before, 5mg on waking and 5mg two hours before the appointment.

**Elderly and debilitated (weak) patients**

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 for all indications should not be more than half of those recommended for adults.

**Kidney or liver impairment**

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

**Use in children**

**Tension and irritability in cerebral spasticity:** Take 5-40mg daily in divided doses.

**Before surgery:** 2-10mg.

**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. Take with you any remaining tablets and the pack so that the medicine can be identified.

**If you forget to take Diazepam Tablets**

Take your dose as soon as you remember and then your next dose at the usual time. However, if it is almost time for your next dose, skip the missed dose and continue with your normal dosing schedule. Do not take a double dose to make up for a forgotten dose.

**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. This medicine should not be stopped suddenly; keep taking it until your doctor tells you how to reduce the dose slowly. 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: 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).

If you stop taking the tablets suddenly you may experience the following withdrawal effects: depression, nervousness, difficulty in sleeping, irritability, sweating, upset stomach/diarrhoea, or the symptoms you are being treated for can come back worse than before. You may also experience mood changes, anxiety, restlessness and changes in sleep patterns. These effects may occur even after taking low doses for a short period of time. Patients at risk of convulsions may be more susceptible to suffering fits on withdrawal.

If you stop taking these tablets suddenly after being treated with high doses of diazepam, 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. The elderly, children and weak patients are more susceptible to side effects.

**Tell your doctor or pharmacist if you notice any of the following side effects listed in the sections below:**

**Serious side effects**

**STOP TAKING the tablets IMMEDIATELY and seek medical help if any of the following occur:**

- 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 effects after stopping treatment and sometimes between doses (for possible symptoms please see section 3 “If you stop taking Diazepam Tablets”)
- confusion
- loss of coordination of muscle movements (ataxia) and other movement disorders, tremor.

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

- muscle weakness
- loss of memory
- difficulty in concentrating
- dizziness
- balance disorders
- 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, restlessness, agitation, irritability, aggressiveness, rages, psychoses, memory loss, delusion, nightmares, inappropriate behaviour or hallucinations. May be or become serious. These side effects are more likely to occur in children or the elderly. Talk to your doctor.
- blood disorders (you may develop sore throats, nose bleeds or infections)
- depression, emotional withdrawal, decreased alertness
- problems sleeping (insomnia)
- low blood pressure, fainting (syncope)
- heart problems such as slow heartbeat (bradycardia), heart failure and cessation of heartbeat (cardiac arrest)
- 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)
- changes in sex drive (libido), impotence, breast enlargement in men.

**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 or double vision, involuntary eye movements (which are reversible after stopping taking diazepam).
- dependence and addiction (see section “How do I know if I am tolerant or addicted?”).

**Drug Withdrawal**

When you stop taking Diazepam Tablets you may experience drug withdrawal symptoms, which include: 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).

**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](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.

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

Keep the package in the outer carton in order to protect from light and moisture.

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 substance.
- The other ingredients are: lactose, microcrystalline cellulose, maize starch, pregelatinised maize starch and magnesium stearate. Also, the 5mg tablets contain quinoline yellow (E104) and the 10 mg tablets contain indigo carmine blue (E132).

**What Diazepam Tablets look like and contents of the pack**

Diazepam 2mg Tablets are white, round, tablets engraved with company logo on one side and a break line and A272 on the other.

Diazepam 5mg Tablets are yellow, round, tablets engraved with company logo on one side and a break line and A273 on the other.

Diazepam 10mg Tablets are blue, round, tablets engraved with company logo on one side and a break line and A278 on the other.

The medicine is available in pack sizes of 28, 56, 84 and 112 tablets (not all packs may be marketed).



**Marketing Authorisation Holder and Manufacturer**

Crescent Pharma Ltd., Key House, Sarum Hill, Basingstoke, RG21 8SR, UK.

**This leaflet was last revised in November 2025.**

If you would like this leaflet in a different format please contact the licence holder at the above address.

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# DIAZEPAM Tablets 2mg, 5mg and 10mg

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.

## 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

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### 1. What Diazepam Tablets is and what it is used for

This medicine has been prescribed for you for relief of anxiety.

It contains the Diazepam which belongs to a class of medicines called benzodiazepines which work by having a calming effect on various functions of the brain.

This medicine has been prescribed to you and should not be given to anyone else.

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 is used to treat a number of conditions including the following:

- short-term relief (2-4 weeks only) of severe anxiety (an emotional state where you may sweat, tremble, feel anxious and have a fast heartbeat); this may occur alone or with difficulty in sleeping or mental health problems
- severe insomnia (difficulty sleeping)
- helping muscle spasms relax and for muscle relax and cerebral palsy (a condition affecting the brain which causes movement problems and rigidity or stiffness) or tetanus
- symptoms of alcohol withdrawal
- with other medicines to treat epilepsy (fits)
- helping patients relax before surgery or dental procedures.

This medicine can also be used for children to help them relax before surgery, to control muscle spasms/twitching caused by tetanus and controlling tension and irritability in 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).

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 stopping 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 or you have a personality disorder.

### 2. What you need to know before you take Diazepam Tablets

#### Do not take Diazepam Tablets if you:

- are allergic (hypersensitive) to diazepam, or other benzodiazepine medicine, or any of the other ingredients of this medicine (listed in section 6)
- have difficulty in breathing or any kind of lung disease e.g. asthma
- suffer from phobias (a fear of a particular object or situation) or other mental illness
- suffer from myasthenia gravis (a condition which causes muscles to weaken and tire easily)
- suffer from severe liver disorders
- suffer from porphyria (an inherited condition causing skin blisters, abdominal pain and brain or nervous system disorders)
- suffer from sleep apnoea (sometimes stop breathing during sleep)
- suffer from depression (with or without anxiety) or hyperactivity
- are planning a pregnancy or are pregnant (see pregnancy and breast-feeding section).

#### Warnings and precautions

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

- have disease of the arteries, kidney or liver
- have breathing difficulties
- smoke
- have problems with your lungs and heart
- have severe kidney failure
- have depression or mental illness
- have a history of alcohol or drug abuse
- have hypoalbuminaemia (low levels of albumin in your blood which can cause swelling)
- are elderly (diazepam may make you confused or clumsy or affect muscles, causing you to fall or injure yourself)
- have a personality disorder
- have epilepsy or history of seizures
- have poor blood supply to the brain (arteriosclerosis)
- have suicidal thoughts
- have recently suffered a bereavement (someone close to you has died).
- 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 Diazepam Tablets 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.

#### 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 as short a 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.'

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: 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.

#### Other medicines and Diazepam Tablets

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines. 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.
- 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.
- *hypericum perforatum* (Perforate St John's wort, a herbal remedy)
- 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 and breast-feeding

Do not take Diazepam if you are pregnant, might become pregnant or breast-feeding. If you and your doctor decide that you should take this medicine towards the end of 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. Also, if you take this medicine regularly during your pregnancy your baby may get withdrawal symptoms.

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask

Product:	Diazepam Tablets 2mg, 5mg, and 10mg - Rusan Pharma
Item Code:	P3631T
Size:	150 x 590 mm
Min. Point size:	8pt
O. Artwork	11/11/25
Proof No.	2
Amendment Date:	12/11/25

Colours Used	
	Process Black
	Keyline - does not print

your doctor or pharmacist for advice before taking this medicine.

#### Driving and using machines

The medicine can affect your ability to drive and operate machinery as it may make you sleepy, dizzy, forgetful or have poor co-ordination along with other side effects that can affect everyday activities (see Possible side effects). These effects may continue into the next day or several days after taking, even after a single dose. You should not drive, operate machinery or take part in such activities where, if affected, you could put yourself or others at risk.

- 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 instruction 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

Your prescriber should have discussed with you how long the course of Diazepam 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.

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 not take Diazepam Tablets for longer than 4 weeks.

The tablets should be swallowed with a drink of water.

This medicine can make you suffer memory loss several hours after taking it. Try to make sure you can have 7 to 8 hours of uninterrupted sleep each night whilst you are taking this medicine.

The recommended dose is:

#### Adults:

- **Relief of severe anxiety and other mental health problems:** Take 5-30mg daily in divided doses.
- **Insomnia associated with anxiety:** Take 5-15mg at bedtime.
- **Cerebral palsy or other spasticities:** Take 5-60mg daily in divided doses.
- **Muscle spasm:** Take 5-15mg daily in divided doses.
- **As additional treatment of some forms of epilepsy:** 2-60mg daily in divided doses.
- **Before surgery:** 5-20mg.
- **Treatment of withdrawal symptoms of alcohol:** Take 5-20mg, repeated if necessary in 2-4 hours.
- **Before dental procedures:** 5mg the night before, 5mg on waking and 5mg two hours before the appointment.

#### Elderly and debilitated (weak) patients

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 for all indications should not be more than half of those recommended for adults.

#### Kidney or liver impairment

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

#### Use in children

##### Tension and irritability in cerebral spasticity:

Take 5-40mg daily in divided doses.

**Before surgery:** 2-10mg.

#### 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. Take with you any remaining tablets and the pack so that the medicine can be identified.

#### If you forget to take Diazepam Tablets

Take your dose as soon as you remember and then your next dose at the usual time.

However, if it is almost time for your next dose, skip the missed dose and continue with your normal dosing schedule. Do not take a double dose to make up for a forgotten dose.

#### 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: 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).

If you stop taking the tablets suddenly you may experience the following withdrawal effects: depression, nervousness, difficulty in sleeping, irritability, sweating, upset stomach/diarrhoea, or the symptoms you are being treated for can come back worse than before. You may also experience mood changes, anxiety, restlessness and changes in sleep patterns. These effects may occur even after taking low doses for a short period of time. Patients at risk of convulsions may be more susceptible to suffering fits on withdrawal.

If you stop taking these tablets suddenly after being treated with high doses of diazepam, 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. The elderly, children and weak patients are more susceptible to side effects.

**Tell your doctor or pharmacist if you notice any of the following side effects listed in the sections below:**

#### Serious side effects

**STOP TAKING the tablets IMMEDIATELY and seek medical help if any of the following occur:**

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 effects after stopping treatment and sometimes between doses (for possible symptoms please see section 3 "If you stop taking Diazepam Tablets")
- confusion
- loss of coordination of muscle movements (ataxia) and other movement disorders, tremor.

Uncommon: (may affect up to 1 in 100 people)

- muscle weakness
- loss of memory
- difficulty in concentrating
- dizziness
- balance disorders
- 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, restlessness, agitation, irritability, aggressiveness, rages, psychoses, memory loss, delusion, nightmares, inappropriate behaviour or hallucinations. May be or become serious. These side effects are more likely to occur in children or the elderly. Talk to your doctor.
- blood disorders (you may develop sore throats, nose bleeds or infections)
- depression, emotional withdrawal, decreased alertness
- problems sleeping (insomnia)
- low blood pressure, fainting (syncope)
- heart problems such as slow heartbeat (bradycardia), heart failure and cessation of heartbeat (cardiac arrest)
- 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)
- changes in sex drive (libido), impotence, breast enlargement in men.

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 or double vision, involuntary eye movements (which are reversible after stopping taking diazepam).
- dependence and addiction (see section "How do I know if I am tolerant or addicted?").

#### Drug Withdrawal

When you stop taking Diazepam Tablets you may experience drug withdrawal symptoms, which include: 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).

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](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.

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

Keep the package in the outer carton in order to protect from light and moisture.

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 substance.
- The other ingredients are: lactose, microcrystalline cellulose, maize starch, pregelatinised maize starch and magnesium stearate. Also, the 5mg tablets contain quinoline yellow (E104) and the 10 mg tablets contain indigo carmine blue (E132).

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

Diazepam 2mg Tablets are white, round, tablets engraved with company logo on one side and a break line and A272 on the other.

Diazepam 5mg Tablets are yellow, round, tablets engraved with company logo on one side and a break line and A273 on the other.

Diazepam 10mg Tablets are blue, round, tablets engraved with company logo on one side and a break line and A278 on the other.

The medicine is available in pack sizes of 28, 56, 84 and 112 tablets (not all packs may be marketed).

**Marketing Authorisation Holder and Manufacturer**  
Crescent Pharma Ltd., Key House,  
Sarum Hill, Basingstoke, RG21 8SR, UK.

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PHARMA CODE

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Min. Point size:	8pt
O. Artwork	11/11/25
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