

Diazepam 2 mg, 5 mg and 10 mg Tablets

Diazepam

SOVEREIGN MEDICAL LOGO

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

- 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.
- 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. 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 effect 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 Tablets
4. Possible side effects
5. How to store Diazepam Tablets
6. Contents of the pack and other information

1. What Diazepam Tablets are and what they are used for

The name of your medicine is Diazepam 2 mg, 5 mg or 10 mg Tablets (referred to as Diazepam Tablets in this leaflet). Diazepam Tablets contain the active ingredient diazepam, which belongs to a group of medicines called benzodiazepines. This medicine has been prescribed for you for the treatment of anxiety, muscle spasms and convulsions (fits). 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 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 to diazepam or to other benzodiazepines or to any of the other ingredients of this medicine (listed in section 6).
- if you have a phobia (a fear of a particular object or situation) or other mental illness
- if you have breathing problems, which may be severe, including slow and/or shallow breathing
- if you have myasthenia gravis (a condition which causes muscles to weaken and tire easily)
- if you suffer from sleep apnoea (a sleep disorder where you have abnormal pauses in breathing during sleep)
- if you have severe liver disorders
- if you have porphyria (an inherited condition causing skin blisters, abdominal pain and brain or nervous system disorders)
- if you suffer from depression (with or without anxiety) or hyperactivity
- if you are planning a pregnancy or are pregnant (see below *Pregnancy and breast-feeding*).

Warnings and precautions

Talk to your doctor or pharmacist before taking Diazepam Tablets

- If you 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.
- If you have previously suffered from withdrawal symptoms such as agitation, anxiety, shaking or sweating, when you have stopped taking alcohol or drugs.
- If you feel you need to take more of <product name> to get the same level of symptom control, this may mean you are developing tolerance to the effects of this medicine or are becoming addicted to it. Speak to your prescriber who will discuss your treatment and may change your dose or switch you to an alternative medication.

- if you have long term kidney, liver, heart or respiratory problems
- if you have a personality disorder
- if you have a history of alcoholism or drug abuse
- if someone close to you has recently died
- if you have low blood levels of a protein called albumin
- if you are elderly (risk of confusion or clumsiness, causing fall or injury)
- if you have a poor blood supply to the brain (arteriosclerosis)
- If you have breathing difficulties
- If you smoke
- If you suffer from depression
- If you have suicidal thoughts
- If you have epilepsy or a history of seizures

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).

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. To reduce the risk you should ensure that you will be able to have uninterrupted sleep of 7-8 hours. 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 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'.

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, including medicines obtained without prescription.

This is especially important if you are taking the following:

- **sodium oxybate** (used to prevent episodes of sudden sleep onset (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.

- **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 and food and drink

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.

Other special warnings

- If you see another doctor or visit a hospital, remember to tell them what medicines you are already taking.
- If you are going to have an operation please tell the anaesthetist that you are taking Diazepam Tablets as this may affect some of the drugs he/she may use.

Pregnancy and breast-feeding

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

You should not take Diazepam Tablets if you are pregnant, planning to become pregnant or are breast-feeding. If you and your doctor decide that you should take Diazepam Tablets late in your pregnancy or during labour, this may harm your baby. Your baby might have a low body temperature, floppiness, breathing problems and difficulty feeding.

If taken regularly during your pregnancy, your baby may develop withdrawal symptoms.

Diazepam can pass into breast milk. Ask your doctor or pharmacist for advice before taking any 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

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

3. How to take Diazepam Tablets

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

You should not take Diazepam Tablets for longer than 4 weeks.

The tablets should be swallowed whole with a glass of water.

Recommended dose

Adults

- **Anxiety or mental health problems:** 5mg-30mg each day, in divided doses.
- To help you sleep: 5mg-15mg at bedtime.
- To help cerebral palsy or other spasticities: 5mg-60mg each day, in divided doses.
- To help control muscle spasm: 5mg-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

Elderly or frail

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.

Renal and/or hepatic impairment

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

Use in children

For tension and irritability in cerebral spasticity: 5mg-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.

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

If you forget to take a dose, just take the next dose at the usual time. 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: see '**Section 2. What you need to know before you take Diazepam Tablets'**

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 in some people, although not everybody gets them.

Serious side effects

If you notice any of the following, stop taking Diazepam Tablets and contact your doctor immediately:

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)
- 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.

Withdrawal symptoms: see **'Section 2. What you need to know before you take Diazepam Tablets'**

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 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 store above 25°C. Keep the container tightly closed and store in the original container or package in order to protect from light.

Do not use this medicine after the expiry date that is stated on the carton, bottle or blister after EXP. This 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

Each tablet contains 2 mg, 5 mg or 10 mg of the active ingredient diazepam.

Diazepam 2 mg and 5 mg Tablets also contain colloidal silicon dioxide, maize starch, magnesium stearate and lactose.

Diazepam 5 mg Tablets also contain yellow iron oxide (E172) and quinoline yellow lake (E104).

Diazepam 10 mg Tablets contain dextrin, maize starch, magnesium stearate, lactose and indigo carmine lake (E132).

What Diazepam Tablets look like and contents of the pack

Diazepam 2 mg Tablets: Flat white tablets with bevelled edges, 8 mm diameter. One face is embossed with "DZ" and "2" separated by a breakline. The reverse face is plain.

Diazepam 5 mg Tablets: Flat, pale yellow tablets with bevelled edges, 8 mm diameter. One face is embossed with "DZ" and "5" separated by a breakline. The reverse is plain.

Diazepam 10 mg Tablets: Flat, blue tablets with bevelled edges, 8 mm diameter. One face is embossed with "DZ" and "10" separated by a breakline. The reverse is plain.

Diazepam 2 mg, 5 mg and 10 mg Tablets are available in blister packs of 28 tablets and pots of 21, 100, 250, 500 and 1000 tablets.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder

Sovereign Medical, Sovereign House, Miles Gray Road, Basildon, Essex, SS14 3FR.

Manufacturer

Waymade Plc, Sovereign House, Miles Gray Road, Basildon, Essex, SS14 3FR.

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PL 06464/1400 Diazepam 2 mg Tablets

PL 06464/1401 Diazepam 5 mg Tablets

PL 06464/1402 Diazepam 10 mg Tablets

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