Package leaflet: Information for the patient

Diazepam 2mg, 5mg, 10mg tablets

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

• Keep this leaflet. You may need to read it again.
• If you have any further questions, ask your doctor or pharmacist.

This medicine has been prescribed for you. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What is this leaflet about?
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
Diazepam belongs to a group of medicines called benzodiazepines. Diazepam helps in the treatment of anxiety, muscle spasms and convulsions (seizures).

Diazepam tablets are used to treat a number of conditions, including:
- 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 heartbeat and may occur alone or with insomnia (trouble sleeping) or medical health problems
- helping muscles relax and for muscle spasm and central pain (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 palsy (a condition associated with a disease or trauma affecting the brain or spinal cord which causes weakness, un-coordinated movements, rigidity and seizures)
• 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 on or 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 benzodiazepines medicines or to any of the other ingredients in your tablets (see 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 fatigue 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 or pharmacist before taking Diazepam tablets:
- you have a history of alcoholism or drug abuse
- have problems with your heart or lungs or have severe kidney failure
- have someone close to you that has recently died
- have low blood levels of a protein called albumin
- you have a personality disorder
- you have a poor blood supply to the brain (cerebrovascular disease)
- 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 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’.

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 sleep attacks)
• antidepressants (e.g. fluoxetine, fluoxetine)
• antipsychotics such as clozapine (to treat mental problems)
• antihistamines (to treat allergies)
• sedatives (used to give calming effects)
• hypnotics (to help you sleep)
• erythromycin (an antibiotic)
• muscle relaxants (e.g. raunethemium, tubocurarine)
• some strong pain killers such as morphine (morphine)
• some anti-inflammatory drugs (such as ibuprofen, naproxen, valdecoxib, celecoxib)
• corticosteroids (medicines used to treat inflammation in the body) as they can weaken the effect of diazepam.

• levodopa (used to treat Parkinson's disease)
• sildenafil (used to treat erectile dysfunction) as it can slow the removal of diazepam from the body and increase its effect.
• ketamine (an anaesthetic) as diazepam increases the effect of ketamine.
• loperamide (to help relieve stomach complaints 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 talk to your doctor or relatives to be aware of the signs and symptoms stated above. Contact your doctor when experiencing such symptoms.

Diazepam tablets with 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 heart or kidney disease and are taking the medicines 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, breastfeeding and fertility
Do not take Diazepam tablets 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 birth weight, 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.

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 intolerance to some sugars contact your doctor before taking this medicine.

3. How to take Diazepam tablets
Always take this medicine exactly as your doctor before taking this medicine.

Very rare (may affect up to 1 in 10,000 people)
- Jaundice (yellowing of your skin or the white of your eyes)
- Anaphylaxis (swelling of your lips, tongue and throat or other symptoms such as sudden wheezing, swelling of your lips, tongue and throat or body, rash, fainting or difficulties to swallow)

Rare (may affect up to 1 in 1,000 people)
- 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 10,000 people)
- Mental side effects such as excitation, agitation, restlessness, irritability, aggressiveness, memory loss, inappropriate behaviour, delusion, rages, phobias, 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 (sleeping problems)
- 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)

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Low levels of white blood cells (leukopenia)
- Older level of a certain enzyme in the blood (aspartate aminotransferase, alanine aminotransferase or bilirubin) (higher level of a certain enzyme in the blood),
- Abnormal liver function tests
- 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 4 if you stop taking Diazepam tablets.

If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

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

Diazepam Tablets
2mg, 5mg, 10mg x 28’s (UK)

2mg: 148x210 (Reel Fed)
Component: Leaflet for Blister pack
Pharmacode: 6800

Date: 21/06/19
Technologist: T. Hull

Technically Approved

Accord BST - Packing Technical Service
BBBA5337 50971104

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148x210 Leaflet Reel Fed Profile (BST)