Diazepam 2mg, 5mg and 10mg tablets

Read all of this leaflet carefully before you start treatment and save it for future reference.

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 symptoms are the same as yours.

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.

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

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

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

- In adults:
  - short term relief (2-4 weeks only) of severe anxiety, which is an emotional state where you may sweat, tremble, feel anxious and have a fast heart beat and may occur alone or with insomnia ( Trouble sleeping) or mental health problems
  - muscle relax and for muscle spasm and cerebral palsy (a condition 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
  - epilepsy (when taken with other medicine)
  - patients with the symptoms of alcohol withdrawal
  - helping muscles relax and for muscle spasm (causing skin blisters, abdominal pain and brain or nervous system disorders)
  - planning a pregnancy or are pregnant (see below Pregnancy and breast-feeding).

- 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 stiffness)
  - helping to treat muscle spasms 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.

2. Before you take

Do not take Diazepam tablets and tell your doctor if you:

- are allergic (hypersensitive) to diazepam or to any of the other ingredients in your tablets (see section 4).
- have problems with your heart and lungs or have severe kidney failure
- have someone close to you who has recently died
- have low blood levels of a protein called albumin
- have a personality disorder
- have a poor blood supply to the brain (arteriosclerosis)
- are elderly

Diazepam tablets can cause confusion and have effects on muscles causing falls and injuries.

- have breathing difficulties
- have suffered a stroke
- have suffered depression
- have suffered from hypoglycaemia
- have epilepsy or have a history of seizures

Other considerations

- Mental side effects – contact your doctor if you experience side effects such as agitation, hyperactivity, restlessness, aggressiveness, nightmares or hallucinations. These side effects are more likely to occur in children or the elderly.
- Amnesia (total or partial memory loss) – you could experience amnesia when taking this medicine. Amnesia is more likely to occur when taking high doses of diazepam.
- Dependence – when taking this medicine there is a risk of dependence, which increases with the dose and duration of treatment and also in patients with a history of alcoholism and drug abuse. Therefore, you should take Diazepam tablets for a short period of time as possible.
- Tolerance – if after a few weeks you notice that the tablets are not working as well as they did when first starting treatment, you should speak to your doctor.

Withdrawal – treatment should be gradually withdrawn. Withdrawal symptoms occur with Diazepam tablets even when normal doses are given for short periods of time. See Section 3, “If you stop taking Diazepam tablets.”

Taking other medicines

Please tell your doctor or pharmacist if you are taking or have taken any other medicines, including medicines obtained without a prescription. Especially:

- anticoagulants (e.g. warfarin, heparin)
- antipsychotics (such as clozapine (to treat mental problems) and risperidone)
- antidepressants
- muscle relaxants (e.g. suxamethonium, tubocurarine)
- some strong pain killers such as morphine (pills) 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.
- sodium valproate, lamotrigine, oxcarbazepine, tiagabine, vigabatrin, gabapentin and pregabalin (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.
- loxapine (to help relieve symptoms when you stop taking opioids).
- nabilone (to treat nausea and vomiting)
- alpha blockers or moxonidine (to lower high blood pressure)

Taking 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 cirrhosis or any of the conditions listed in section 2, this could possibly increase the sedative effects of Diazepam tablets and you should speak to your doctor or pharmacist.

Drinks containing caffeine may reduce the effects of diazepam.

Pregnancy and breast-feeding

You should not take Diazepam tablets if you are pregnant, planning to become pregnant or are breast feeding. If you take Diazepam tablets late in pregnancy or during labour your baby might have...
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 while, 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.

Important information about some of the ingredients of Diazepam tablets

Diazepam tablets contain lactose (a type of sugar). If you have been told that you have intolerance to some sugars contact your pharmacist how to dispose of medicines properly.

3. How to take

Always take Diazepam tablets exactly as your doctor has told you. You should not take Diazepam tablets for longer than 4 weeks. You should check with your doctor or pharmacist if you are not sure. Swallow the tablets whole, with a glass of water.

Doses

Adults

- Anxiety or mental health problems: 5mg-30mg each day, in divided doses.
- To help you sleep: 5mg-15mg at bedtime.

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.

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.

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

If you take more Diazepam tablets than you should

If you (or someone else) swallow a lot of tablets at the same time, or you think a child may have swallowed any, contact your nearest hospital casualty department or tell your doctor immediately. Signs of an overdose include dizziness 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 (unreversible unconsciousness), reflex problems and breathing difficulties.

If you forget to take Diazepam tablets

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

If you stop taking Diazepam tablets

- Do not stop taking your medicine without telling your doctor as he may wish to gradually reduce the number of tablets you take before stopping them completely.
- If you stop taking Diazepam tablets suddenly, you may experience unpleasant side effects including depression, nervousness, irritability, sweating or diarrhoea. If you have been taking a high dose, you may occasionally experience confusion, convulsions or unusual behaviour.
- Treatment should be gradually withdrawn otherwise the symptoms you are being treated for may return more intensely than before (rebound insomnia and anxiety). The risk of this happening is greater when you stop taking Diazepam suddenly. You may also experience mood changes, anxiety, restlessness or changes in sleep patterns.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

4. Possible Side Effects

Like all medicines, Diazepam tablets can cause side-effects, although not everybody gets them.

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

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

Common: affects 1 to 10 users in 1,000

- Respiratory depression (very slow and/or shallow breathing)

Rare: affects 1 to 10 users in 10,000

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

Very rare: affects less than 1 user in 10,000

- Metaphor (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:

- Common: affects more than 1 user in 10
- Drowsiness

Common: affects 1 to 10 users in 100

- Tablets:
  - Withdrawal symptoms (for possible symptoms please see if you stop taking Diazepam tablets in Section 3)
  - Confusion

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/yellowcard

By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store

Keep out of the reach and sight of children. Do not store above 25°C.

Do not use Diazepam tablets after the expiry date stated on the label/carton/bottle. The expiry date refers to the last day of that month.

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

6. Further Information

What Diazepam tablets contain:

- The main active substance (the ingredient that makes the tablet work) is diazepam. Each tablet contains either 2mg, 5mg or 10mg of the active ingredient.
- The other ingredients are lactose, magnesium stearate, maize starch and steanic acid.
- The 5mg tablets also contain quinoline yellow (E104).
- The 10mg tablets also contain HT Lake yellow (E112).

What Diazepam tablets looks like and contents of the pack

Diazepam tablets are uncoated tablets in blister packs of 28’s: white, 5mg, yellow, 10mg–blue. Pack sizes are 28 tablets.

Marketing Authorisation Holder and Manufacturer:

Actavis, Barnstaple, EX32 8NS, UK.

Date of Revision: May 2014