

DIAZEPAM 2 mg, 5 mg & 10 mg TABLETS

Read all of this leaflet carefully before you start taking this medicine.

- **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 become serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

THIS LEAFLET CONTAINS

1. What Diazepam is for
2. Before you take Diazepam
3. How to take Diazepam
4. Possible side effects
5. How to store Diazepam
6. Further information

1. WHAT DIAZEPAM IS FOR

Diazepam belongs to a group of medicines called benzodiazepines. It can be used to treat a number of conditions, including:

In adults:

- the **short-term** relief of severe anxiety
- insomnia (difficulty in sleeping) due to anxiety
- muscle spasms and 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)
- some forms of epilepsy (when taken with other medicines)
- the symptoms of alcohol withdrawal
- before dental or surgical procedures to help with relaxation and to cause sleepiness

In children:

- nightmares and sleepwalking
- tension and irritability caused by cerebral spasticity

If you are not sure why you have been prescribed these tablets then please ask your doctor.

2. BEFORE YOU TAKE DIAZEPAM

Do not take Diazepam and tell your doctor if you:

- are allergic to Diazepam, any of the other ingredients in the tablets (listed in section 6 of this leaflet) or to other benzodiazepines
- have severe liver, lung or breathing problems
- have muscle weakness sometimes causing difficulty breathing (myasthenia gravis)
- suffer from breathing problems whilst asleep (sleep apnoea)
- suffer from depression, mental health problems, irrational fears (phobias) or obsessions

Take special care with Diazepam

Tell your doctor **before** you take this medicine if you:

- have a history of alcohol or drug abuse
- suffer from a personality disorder
- have recently suffered a loss or bereavement
- are elderly or have problems with your liver, kidneys or lungs
- have weak or tired muscles
- suffer from an inherited iron disorder (porphyria)

Medicines such as Diazepam may lead to addiction. Any risk is more likely with high doses, prolonged treatment or if you have a history of alcohol or drug abuse or you suffer from a personality disorder.

Taking other medicines

Tell your doctor or pharmacist if you are taking or have recently taken **any** other medicines, even medicines bought without a prescription.

In particular, tell your doctor or pharmacist if you are taking any of the following medicines, as they may

affect how Diazepam tablets work:

- Medicines to treat depression such as Fluvoxamine or Mirtazapine
- Medicines to treat mental health problems such as Olanzapine, Prochlorperazine or Zolpidem
- Medicines to calm you down or to help you sleep
- Sodium oxybate to reduce daytime sleepiness or sudden loss of muscle strength
- Disulfiram or Lofexidine for drug dependence
- Strong pain killers or general anaesthetics
- Nabilone to treat sickness caused by chemotherapy
- Medicines to treat epilepsy such as Phenytoin, Valproate or barbiturates
- Levodopa to treat Parkinson's disease
- Medicines to treat high blood pressure or heart failure such as Moxonidone, Diazoxide, Hydralazine or Minoxidil
- Medicines to increase urine production such as Diuretics
- Muscle relaxants such as Baclofen or Tizanidine
- Isoniazid or Rifampicin to treat bacterial infections
- Fosamprenavir or Ritonavir to treat viral infections
- Medicines to treat ulcers such as Cimetidine, Omeprazole or Esomeprazole
- Antihistamines for allergies
- Theophylline for asthma

If you go into hospital or have treatment for other conditions, tell the doctor that you are taking Diazepam.

Taking Diazepam with food and drink

Alcohol may increase the sedative effects of Diazepam and make you feel very sleepy. **Do not drink alcohol** whilst taking Diazepam.

Pregnancy and breast-feeding

Do not take Diazepam if you are pregnant, planning to become pregnant or you are breast-feeding, unless your doctor has told you to.

If you take this medicine late in your pregnancy or during labour your baby might have an irregular heart rate, a low body temperature, floppiness, and breathing and feeding difficulties.

If you take this medicine regularly during late pregnancy, your baby may become dependent on Diazepam and develop withdrawal symptoms after birth.

Make sure you follow your doctor's advice.

Driving and using machines

Diazepam can affect your ability to drive and use machines as it may make you sleepy or dizzy. Do not drink alcohol as it can make these effects worse.

Do not drive or use machinery while taking Diazepam 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:

- Diazepam 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

Diazepam 2 mg, 5 mg and 10 mg tablets contain **lactose** (a type of sugar). If you know you have an intolerance to some sugars contact your doctor before taking this medicine.

3. HOW TO TAKE DIAZEPAM

Always take Diazepam tablets exactly as your doctor has told you. Take this medicine by mouth.

When taking Diazepam tablets try to make sure you sleep well for 7-8 hours per night.

Dosage

You will be prescribed the lowest effective dose for the shortest time necessary to treat your symptoms. This will reduce the risk of addiction.

Typically Diazepam will not be prescribed for more than 4 weeks.

Adults:

Anxiety: Typical dose is 2 mg three times a day. This can be increased to 15-30 mg daily in divided doses.

Insomnia in association with anxiety: Typical dose is 5-15 mg at bedtime.

Muscle spasms: Typical dose is 2-15 mg daily in divided doses.

Cerebral spasticity or epilepsy: Typical dose is 2-60 mg daily depending on your response to the medicine.

Alcohol withdrawal symptoms: Typical dose is 5-20 mg, which may be repeated after two to four hours if necessary.

Before dental or surgical procedures: Typical dose is 5 mg the night before the operation then 5 mg two hours before the operation.

Elderly or debilitated (those that are weak or feeble): Typically require half the adult dose, as you are more likely to be sensitive to the effects of Diazepam. Follow your doctor's advice.

If you have **liver or kidney problems or breathing difficulties** you may also require lower doses.

Children:

Nightmares and sleepwalking: Typical dose is 1-5 mg at bedtime.

Tension and irritability in cerebral spasticity: Typical dose is 2-40 mg daily in divided doses.

If you take more Diazepam than you should

Contact your doctor or go to a hospital immediately. Show them the package or container. Symptoms of an overdose may include drowsiness, confusion, tiredness, breathing problems, difficulty in swallowing, difficulty in controlling movements, low blood pressure or falling into a coma.

If you forget to take Diazepam

Don't worry, just take your next scheduled dose at the correct time. Do not take a double dose to make up for the one you have missed.

If you suddenly stop taking Diazepam

The risk of withdrawal symptoms is greater. Your doctor will **gradually** reduce your dose.

Withdrawal symptoms may include headache, sweating, diarrhoea, muscle pain, tension, extreme anxiety, depression or irritability and occasionally hallucinations, fits, unusual behaviour, numbness and tingling of the hands and feet or sensitivity to light, noise or touch.

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 can cause side effects, although not everybody gets them.

If you get any of the following side effects, STOP TAKING this medicine and tell your doctor at once:

- feeling restless, agitated or irritated
- nightmares or hallucinations (hearing or seeing things that are not there)
- aggressive outbursts or rages
- unusual behaviour or false beliefs (delusions)

Other side effects include:

The most common side effects are:

- feeling sleepy, light-headed
- unsteadiness
- clumsiness and loss of co-ordination

You could notice the above common side effects even after a single dose and they may continue for more than 24 hours. If you are elderly you are more likely to suffer from side effects, especially confusion and loss of co-ordination.

Other side effects that occur less often are:

- loss of memory
- numbed emotions
- headache
- dizziness or a feeling of spinning (vertigo)

- reduced alertness and tiredness
- low blood pressure
- stomach upsets
- skin rashes
- muscle weakness, shaking (tremor)
- problems with your vision
- difficulty in speaking
- making more saliva than usual
- changes in your sex drive
- difficulty passing urine.
- loss of control of your bladder or bowels (incontinence)

A few cases of unusual bleeding or bruising of the skin, feeling feverish or yellowing of the skin and whites of the eyes (jaundice) have been known to occur. If this happens contact your doctor immediately.

Reporting of side effects

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

You can also report side effects directly via 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 DIAZEPAM

Keep out of the sight and reach of children.

Do not store above 25°C. Store in the original package to protect from light or store in the original container and keep the container tightly closed.

Do not use these tablets after the expiry date, which is stated on the package or container. 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 active ingredient in Diazepam 2 mg, 5 mg and 10 mg tablets is diazepam.

The other ingredients in the 2 mg tablets are lactose, maize starch, pregelatinised starch and magnesium stearate.

The other ingredients in the 5 mg tablets are lactose, maize starch, pregelatinised starch, magnesium stearate, dried aluminium oxide and quinoline yellow (E104).

The other ingredients in the 10 mg tablets are lactose, maize starch, magnesium stearate and indigo carmine (E132).

What Diazepam tablets look like and contents of the pack

Diazepam 2 mg tablets are round white tablets with the marking MP57 on one side.

Diazepam 5 mg tablets are round pale yellow tablets with the marking MP58 on one side.

Diazepam 10 mg tablets are round pale blue tablets with the marking MP59 on one side and a break line engraved on the other.

The tablets come in containers of 14, 15, 21, 28, 30, 50, 56, 60, 84, 100, 250, 500 and 1000 tablets and in blister packs of 14 and 28 tablets. Not all pack sizes may be marketed.

Marketing Authorisation Holder

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For more information about this product, please contact the Marketing Authorisation Holder.

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