

Package leaflet: Information for the user

Diazepam 2 mg tablets
Diazepam 5 mg tablets
Diazepam 10 mg tablets

Diazepam

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 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, tell your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet:

- 1. What Diazepam is and what it is used for**
- 2. What you need to know before you take Diazepam**
- 3. How to take Diazepam**
- 4. Possible side effects**
- 5. How to store Diazepam**
- 6. Contents of the pack and other information**

1. What Diazepam is and what it is used for

Diazepam contains the active substance diazepam which belongs to a group of medicines called benzodiazepines. Diazepam has anxiolytic, sedative and muscle relaxant effect.

Diazepam is used:

- in the treatment of anxiety.
- in the treatment of muscle spasms, including those caused by cerebral spasticity (originates in the brain).
- for symptoms of alcohol withdrawal.
- to provide sedation before operations (premedication).

Your doctor may prescribe Diazepam for other uses. Please follow your doctor's instructions.

2. What you need to know before you take Diazepam

Do not take Diazepam:

- if you are allergic to diazepam or any of the other ingredients of this medicine (listed in section 6) or to other benzodiazepine medicines.
- if you have a condition called myasthenia gravis 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 acute respiratory depression (slow and/or shallow breathing).

Warnings and precautions

Talk to your doctor or pharmacist before taking Diazepam:

- if you have a history of alcoholism or drug abuse
- if you are elderly. Diazepam can cause confusion and have effects on muscles causing falls and injuries.
- if you have breathing problems
- if you suffer from depression
- if you have suicidal thoughts
- if you 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

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 for as 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 even when normal doses are given for short periods of time. See Section 3, 'If you stop taking Diazepam'.

Other medicines and Diazepam

Tell your doctor or pharmacist if you are taking have recently taken or might take any other medicines. Especially:

- 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)
- muscle relaxants (e.g. suxamethonium, tubocurarin)
- opioids (strong pain killers such as morphine, medicines for substitution therapy and some cough medicines). Concomitant use of diazepam and opioids 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 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
- barbiturates such as phenobarbital (to treat epilepsy and mental disorders)

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. phenytoin and carbamazepine, as these can reduce the effect of diazepam. Diazepam can furthermore affect how phenytoin works.
- theophylline (to treat asthma and other breathing disorders), as it can weaken the effect of diazepam.
- cimetidine, omeprazole or esomeprazole (stomach acid reducing medicines), as these can cause diazepam to be removed from the body more slowly than usual.
- rifampicin (an antibiotic) as this can cause diazepam to be removed from the body more quickly than usual. The effect of diazepam can be weakened.
- atazanavir, ritonavir, delavirdine, efavirenz, indinavir, nelfinavir 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.
- 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.

Diazepam with food and drink and alcohol

Do not drink alcohol while you are taking diazepam. Alcohol may increase the sedative effects of Diazepam and make you very sleepy.

You should not drink grapefruit juice while taking diazepam as it causes diazepam to be removed from the body more slowly and increases the risk of side effects.

Pregnancy and breast-feeding

Ask your doctor or pharmacist for advice before taking any medicine.

You should not take Diazepam if you are pregnant, planning to become pregnant or are breast-feeding. If you take Diazepam late in pregnancy or during labour your baby might have a low body temperature, floppiness and breathing difficulties. If taken regularly during late pregnancy, your baby may develop withdrawal symptoms.

Driving and using machines

Diazepam may make you feel sleepy and affect your concentration. It may also affect how your muscles work. These effects may continue for several days after discontinuation of treatment with diazepam. Do not drive or use any tools or machines if you are affected in this way.

Diazepam contains lactose

Diazepam contains 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

Always take this medicine exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure.

Swallow the tablets with a glass of water.

[For 5 mg and 10 mg tablets:]

The tablets can be divided into equal halves.

Your doctor will decide the appropriate dose and for how long you need to take the tablets. The usual duration of treatment is not longer than 4 weeks. If needed, your doctor might increase the duration of treatment.

The usual doses:

Adults

For anxiety:

2-5 mg diazepam 2-3 times daily. The dose can be increased up to a maximum of 30 mg daily in 2-4 divided doses.

For treatment of muscle spasm:

Up to 15 mg diazepam daily in 2-4 divided doses.

For treatment of muscle spasms in cerebral spasticity:

Up to a maximum of 60 mg daily in 3-4 divided doses.

For treatment of alcohol withdrawal symptoms:

5-20 mg diazepam which may be repeated once after 2-4 hours if necessary, or 10 mg diazepam 3-4 times on the first day. After the first day, the dose is usually lowered to 5 mg diazepam 3-4 times daily as needed. In severe cases, your doctor may use other dosing schedules and treatment might need to take place in a hospital setting.

Premedication before operation:

5-20 mg diazepam once.

Elderly patients

If you are elderly or frail you are likely to be more sensitive to the effects of Diazepam and your dose needs to be reduced. Your doctor will decide how much Diazepam you should be given and how often. Usual starting dose is 2-2.5 mg once or twice daily.

Impaired kidney function

Dose adjustment is usually not necessary.

Impaired liver function

If you suffer from cirrhosis or other liver problems your dose needs to be reduced.

Overweight patients

If you are overweight, it may take longer time for the medicine to work. Furthermore, the effects of Diazepam may take longer time to wear off including possible side effects.

Use in children and adolescents

Children above 6 years of age and adolescents

The child's doctor will decide how much Diazepam should be given and how often. The usual dose is 0.1-0.3 mg/kg body weight daily in 2-4 divided doses.

If you take more Diazepam than you should

If you have taken too many tablets (more than prescribed), 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 loss of coordination of muscle movements, sleep-like drowsy state, confusion, slurred speech and muscle weakness. An extreme overdose may lead to coma (unrousable unconsciousness), low body temperature (hypothermia), low blood pressure, slow pulse and severe breathing difficulties.

If you forget to take Diazepam

If you forget to take a dose take it as soon as you remember it. If you are about to take the next dose, skip the missed dose. Do not take a double dose to make up for a forgotten dose.

If you stop taking Diazepam

Do not stop taking your medicine without talking to your doctor. You should gradually reduce the number or strength of tablets you take before stopping them completely.

If you stop taking Diazepam suddenly, you may experience withdrawal symptoms including: anxiety, panic attack, palpitations (strong and pounding heartbeat), sweating, tremor, stomach problems, irritability, aggression, sensory disorder, muscle spasms, generally feeling unwell, loss of appetite, insomnia, mental side effects such as severe confusion and seizures.

The likelihood and severity of withdrawal symptoms depends on the duration of treatment, dose strength and degree of dependency.

If you have epilepsy or history of seizures and suddenly stop taking Diazepam, there is a risk of convulsions or long-lasting epileptic seizure. There is also risk of seizures if you have an alcohol or drug abuse problem and suddenly stop taking Diazepam.

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.

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:

Uncommon: 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

- 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: affects more than 1 user in 10

- Drowsiness

Common: affects 1 to 10 users in 100

- Fatigue
- Withdrawal symptoms (for possible symptoms please see in Section 3)
- Confusion
- Loss of coordination of muscle movements (ataxia) and other movement disorders, tremor

Uncommon: affects 1 to 10 users in 1,000

- 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: affects 1 to 10 users in 10,000

- Mental side effects such as excitation, agitation, restlessness, irritability, aggressiveness, memory loss, delusion, rages, psychoses, inappropriate behaviour, 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 poverty
- 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)
- Enlargement of mammary glands in men
- Impotence, changes in sexual drive (libido)

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

- 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).

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 HPRA Pharmacovigilance, Earlsfort Terrace, IRL - Dublin 2; Tel: +353 1 6764971; Fax: +353 1 6762517. Website: www.hpra.ie; E-mail: medsafety@hpra.ie. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Diazepam

Keep this medicine out of the sight and reach of children.

<Blisters>

This medicinal product does not require any special storage conditions.

<HDPE tablet container>

<2 mg: 25, 100, 250 and 500 tablets.> Do not store above 30°C

<5 mg: 25, 100, 250 and 500 tablets.> Do not store above 30°C

<10 mg: 25, 200, 250 and 500 tablets.> This medicinal product does not require any special storage conditions.

Do not use this medicine after the expiry date which is stated on the blister/label/carton after 'EXP'.

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 to protect the environment.

6. Contents of the pack and other information

What Diazepam contains

- The active substance is diazepam. Each tablet contains 2 mg, of the active ingredient.
- The active substance is diazepam. Each tablet contains 5 mg of the active ingredient.
- The active substance is diazepam. Each tablet contains 10 mg of the active ingredient.
- The other ingredients are lactose monohydrate, cellulose (powdered), maize starch and magnesium stearate.

What Diazepam look like and contents of the pack

Diazepam 2 mg are white, round, flat and bevelled tablets, 5.0 mm in diameter, with 'D' engraved on one side and '2' engraved on the other.

Diazepam 5 mg are white, round, flat and bevelled tablets, 8.0 mm in diameter, with a score line on one side and 'D5' engraved on the other. The tablet can be divided into equal halves.

Diazepam 10 mg are white, round, flat and bevelled tablets, 11.0 mm in diameter, with a score line on one side and 'D10' engraved on the other. The tablet can be divided into equal halves.

PVC-Aluminium blisters

Pack sizes: 10, 30, 40, 50, 90 and 100 tablets

PVC-Aluminium perforated unit dose blisters

Pack sizes: 50 x 1 tablets

HDPE tablet container with child-resistant PP caps

Pack sizes: 25, 100, 250 and 500 tablets

Not all pack sizes may be marketed.

Marketing Authorisation Holder

Accord Healthcare Ireland Ltd,
Euro House,
Euro Business Park,
Little Island,
Cork T45 K857,
Ireland

Manufacturer

Actavis Group PTC ehf
Reykjavíkurvegur 76-78
220 Hafnarfjörður
Iceland

Aurobindo BV
Baarnsche Dijk 1
3741 LN Baarn
The Netherlands

Balkanpharma Dupnitsa AD
3 Samokovsko Shosse Str.
Dupnitsa 2600
Bulgaria

Merckle Ulm
Graf Arco Straße 3
89079 Ulm
Germany

This leaflet was last approved in April 2020.