

Package leaflet: information for the user

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, talk to 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 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
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6. Contents of the pack and other information

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

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

Diazepam Tablets are used:

In adults

- short-term (2-4 weeks) symptomatic treatment of anxiety that is severe, disabling or subjecting the individual to extreme distress
- Symptomatic treatment of acute alcohol withdrawal.

2. What you need to know before you take Diazepam Tablets

Do not take Diazepam Tablets if you:

- are **allergic** (hypersensitive) to diazepam or to other benzodiazepine medicines or to any of the other ingredients of this medicine (see section 6).
- have a condition called **myasthenia gravis** which causes muscles to weaken and tire easily.
- suffer from **sleep apnoea** (a sleep disorder where you have abnormal pauses in breathing during sleep).
- have **severe liver** disorders.
- have **acute respiratory depression** (slow and/or shallow breathing).
- have **acute intoxication with other CNS active substances** (e.g. hypnotics, analgesics, antidepressants, antipsychotics).

Warnings and Precautions

Talk to your doctor before taking this medicine if you:

- have a history of **alcoholism** or **drug abuse**
- are **elderly**. This **medicine can cause confusion and have effects on muscles causing falls and injuries.**

- **have breathing problems**
- **suffer from depression**
- have **suicidal thoughts**
- have **epilepsy** or a history of **seizures**

Children and adolescents

This medicine should not be used in children and adolescents as safety and efficacy in this age group are not known.

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 this medicine 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 this medicine even when normal doses are given for short periods of time. See Section 3, '**If you stop taking this medicine.**
- When benzodiazepines with a long duration of action are being used it is important to warn against changing to a benzodiazepine with a short duration of action, as withdrawal symptoms may develop.

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 a prescription. 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)
- some **strong pain killers** such as **morphine** (opioids)
- 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.

Risks from Concomitant Use with Opioids:

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 death. Because of this, concomitant use should only be considered when other treatment options are not possible.

If Diazepam Tablets even so are used together with opioids the dosage and duration of concomitant treatment should be limited.

Please tell your doctor about all opioid medicines you are taking, and follow your doctor's dosage recommendation closely

Diazepam Tablets with drink and alcohol

Do not drink alcohol while you are taking diazepam. Alcohol may increase the sedative effects of this medicine 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

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. If you take this medicine 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.

You should not breast-feed during treatment with Diazepam Tablet as it passes into breast milk.

Driving and using machines

This medicine 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.

This medicine can affect your ability to drive. Do not drive whilst taking this medicine until you know how this medicine affects you. It may be an offence to drive if your ability to drive safely is affected.

Diazepam Tablet contains lactose

This medicine 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 Tablets

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

Swallow the tablets with a glass of water.

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 including tapering off process. If needed, your doctor might increase the duration of treatment.

The usual doses:

Adults

For anxiety: 2 mg to 5 mg diazepam 2 to 3 times daily. In severe cases, your doctor may decide to increase the dose depending on your condition up to a maximum of 30 mg daily in 2 to 4 divided doses.

For treatment of alcohol withdrawal symptoms: 5 mg to 20 mg diazepam which may be repeated once after 2 to 4 hours if necessary.

In order to obtain suitable doses of less than 5mg diazepam alternative products have to be used.

Elderly patients

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

In order to obtain suitable doses of less than 5mg diazepam alternative products have to be used.

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.

If you take more Diazepam Tablets 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 Tablets

Take your dose as soon as you remember but do not take a double dose to make up for a forgotten tablet.

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

If you stop taking Diazepam Tablets

- 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 this medicine 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 this medicine, 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 this medicine.

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. These effects are normally mild to moderate in nature.

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: 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 skin rash.

Rare: may affect up to 1 in 1,000 people

- Blood dyscrasia (with symptoms such as persistent fever, bruising, bleeding, paleness)

- Mental side effects such as excitation, agitation, restlessness, irritability, aggressiveness, memory loss, 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 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 or pharmacist. This includes any possible side effects not listed in this leaflet. By reporting side effects you can help provide more information on the safety of this medicine.

For Ireland- 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

5. How to store Diazepam Tablets

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

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

The expiry date refers to the last day of that month

This medicinal product does not require any special storage conditions.

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 Tablet contains

- The active substance (the ingredient that makes the tablet work) is diazepam. Each tablet contains 5 mg or 10 mg of the active ingredient.
- The other ingredients are lactose monohydrate, maize starch, sodium starch glycolate (Type A), talc, magnesium stearate, ferric oxide yellow (for 5 mg), and lake of indigo carmine (for 10 mg).

What Diazepam Tablets look like and contents of the pack

5 mg: Pale yellow mottled, round, approximately 8.0 mm in diameter, flat, bevel edged tablets, debossed with 'CY' on one side and plain on other side

10 mg: Pale blue mottled, round, approximately 8.5 mm in diameter, flat, bevel edged tablets, debossed with 'CZ' on one side and plain on other side

PVC/PVdC -Aluminium blisters

Pack sizes: 10, 20, 25, 28, 30, 40, 50, 60, 90 or 100 tablets in a carton.

HDPE containers

Pack sizes: 25,30 tablets

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder

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

Manufacturer

Wessling Hungary Kft
Anonymus ut 6., Budapest 1045,
Hungary

Accord Healthcare Polska Sp.z o.o.,
ul. Lutomska 50,95-200 Pabianice, Poland

This medicinal product is authorised in the Member States of the EEA under the following names:

Name of the Member State	Name of the medicinal product
Austria	Diazepam Accord 5/10 mg Tabletten
Cyprus	Diazepam Accord 5/10 mg Tablets
Bulgaria	Diazepam Accord 5/10 мг таблетки
Germany	Diazepam Accord 5/10 mg Tabletten
Denamrk	Diazepam Accord 5 mg tableter
Estonia	Diazepam Accord
Finland	Diazepam Accord 5/10mg tabletti
Ireland	Diazepam 5/10 mg Tablets

Malta	Diazepam 5/10 mg Tablets
Norway	Diazepam Accord
Poland	Codez
Sweden	Diazepam Accord 5/10mg tableter
Slovakia	Diazepam Accord 5/10mg tablety
France	DIAZEPAM ACCORD 5mg/10mg comprimé

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