

Package leaflet: Information for the patient

Diazepam 2mg/5ml Oral Solution Sugar Free

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.
- The full name of this medicine is Diazepam 2mg/5ml Sugar Free Oral Solution but within this leaflet it will be referred to as Diazepam Oral Solution.

What is in this leaflet

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

1. What Diazepam oral solution is and what it is used for

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

In Adults

- Short term relief (14 days) of severe anxiety that may occur alone or with insomnia (trouble sleeping) or mental health problems
- In selected cases of spasticity in cerebral palsy and in the treatment of other forms of muscle spasm
- In the control of muscle spasm in tetanus
- In the treatment of some forms of epilepsy
- To relieve the symptoms of acute alcohol withdrawal.

In Children

- To treat night terrors or sleep walking in children
- In the control of muscle spasm in tetanus
- To control tension and irritability in selected cases of spasticity in cerebral palsy.

Both adults and children can take a small dose of Diazepam before an operation to help with relaxation and to cause sleepiness.

2. What you need to know before you take Diazepam oral solution

- Do not take Diazepam oral solution if you:
- are **allergic** to diazepam, benzodiazepine medicines, or to any of the other ingredients of this medicine (listed in section 6)
 - have a **phobia** or other **mental illness** or are **hyperactive**
 - breathing problems, which may be severe, including slow and/or shallow breathing
 - have **myasthenia gravis** (a condition 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**
 - planning a **pregnancy** or are **pregnant** (see below 'Pregnancy and breast-feeding')
 - untreated **depression** (with or without anxiety).

Warnings and precautions

Talk to your doctor or pharmacist before taking Diazepam oral solution if you:

- have a history of alcoholism or **drug abuse**
- have **kidney or liver problems**
- have had someone **close to you** recently **die**
- are **elderly**. Diazepam oral solution can cause confusion and have effects on muscles causing falls and injuries.
- have **breathing problems**
- have **suicidal thoughts**
- have **epilepsy** or a history of **seizures**
- have **low blood levels** of a protein called albumin
- have a **personality disorder**
- have a poor blood supply to the brain (**arteriosclerosis**)
- have **porphyria** (an inherited condition causing skin blisters, abdominal pain and brain or nervous system disorders)

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 oral solution for as short period of time as possible.
- **Tolerance** – if after a few weeks you notice that the oral solution is not working as well as it did when first starting treatment, you should go and see your doctor.
- **Withdrawal** – treatment should be gradually withdrawn. Withdrawal symptoms occur with Diazepam oral solution even when normal doses are given for short periods of time. Anxiety and insomnia may reoccur on stopping treatment (**Rebound phenomena**). See Section 3, 'If you stop taking Diazepam'.

Children and adolescents

Use in children below 6 months is not recommended. Paradoxical side effects are more likely to occur in children (see section 4).

Other medicines and Diazepam oral solution

Do not take diazepam oral solution and tell your doctor or pharmacist if you are taking:

- **amrenavir, atazanavir, ritonavir, delavirdine, efavirenz, indinavir, nelfinavir, saquinavir or zidovudine** (antivirals). These can cause diazepam to be removed from the body more slowly than usual and therefore increase the risk of side effects, such as making you feel sleepy for longer or cause difficulty breathing.
- **sodium oxybate** (for narcolepsy). Enhanced effect of sodium oxybate when taken with Diazepam.

Concomitant use of diazepam oral solution and opioids (strong pain killers, medicines for substitution therapy and some cough medicines) increases the risk of drowsiness, difficulties in breathing (respiratory depression) and coma which 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 oral solution 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.

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)
- **erythromycin** (an antibiotic)
- **muscle relaxants** (e.g. suxamethonium, tubocurarin)
- some **strong pain killers** such as **morphine** (opioids) may give you a heightened sense of wellbeing 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) or **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
- **fluconazole, itraconazole, ketoconazole or voriconazole** (anti-fungal medicines). These can cause diazepam to be removed from the body more slowly than usual and therefore increase the risk of side effects, such as making you feel sleepy for longer or cause difficulty breathing. 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. This can cause diazepam to be removed from the body more quickly than usual.
- **cimetidine, omeprazole or esomeprazole** (stomach acid reducing medicines), as these can cause diazepam to be removed from the body more slowly than usual.
- **rifampicin**, to treat infections (an antibiotic) as this can cause diazepam to be removed from the body more quickly than usual. The effect of diazepam can be weakened.

- **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.
- **lofexidine** (to help relieve symptoms when you stop taking opioids)
- **nabilone** (to treat nausea and vomiting)
- **alpha blockers or moxonidine** (to lower high blood pressure)

Diazepam oral solution with food, drink and alcohol

Do not drink alcohol while you are taking Diazepam oral solution. Alcohol may increase the sedative effects of Diazepam oral solution 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 oral solution and you should speak to your doctor or pharmacist.

Drinks containing caffeine may reduce the effects of diazepam.

Pregnancy and breast-feeding

Do not take Diazepam oral solution if you are pregnant, planning to have a baby or are breast feeding. If you take Diazepam oral solution 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. Ask your doctor or pharmacist for advice before taking this medicine.

Driving and using machines

Diazepam oral solution may make you sleepy, forgetful, have poor co-ordination along with other side effects that can affect everyday activities (see section 4). 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 oral solution contains Propylene glycol, Sorbitol, Propyl parahydroxybenzoate (E216), Methyl parahydroxybenzoate (E218) and Glycerol

Diazepam oral solution contains 409mg Propylene glycol per 5ml. If your child is less than 5 years old, talk to your doctor or pharmacist before giving them this medicine, in particular if they use other medicines that contain propylene glycol or alcohol. If you suffer from a liver or kidney disease, do not take this medicine unless recommended by your doctor. Your doctor may carry out extra checks while you are taking this medicine.

Diazepam oral solution contains 1.91g to 2.58g of sorbitol per 5ml solution. Sorbitol is a source of fructose. If your doctor has told you that you (or your child) have an intolerance to some sugars or if you have been diagnosed with hereditary fructose intolerance (HFI), a rare genetic disorder in which a person cannot break down fructose, talk to your doctor before you (or your child) take or receive this medicine. Sorbitol may cause gastrointestinal discomfort and mild laxative effect. Calorific value 2.6 kcal/g sorbitol.

Diazepam oral solution contains 2.500mg of Propyl parahydroxybenzoate (E216) per 5ml solution and 5.000mg of Methyl parahydroxybenzoate (E218) per 5ml solution. May cause allergic reactions (possibly delayed).

Diazepam oral solution contains 0.63g of glycerol per 5ml solution. May cause headache, stomach upset and diarrhoea in doses higher than 31mg.

Information on sodium content

This medicine contains less than 1mmol sodium (23mg) per ml, that is to say essentially 'sodium-free'.

3. How to take Diazepam oral solution

Always take this medicine exactly as your doctor has told you. **You should not take Diazepam oral solution for longer than 4 weeks.** Check with your doctor or pharmacist if you are not sure. You should make sure you are able to have 7-8 hours of uninterrupted sleep.

The recommended dose is: Adults

- Anxiety or mental health problems: 2mg-30mg each day, in divided doses
- Insomnia associated with anxiety: 5mg-15mg at bedtime
- Spasticity in cerebral palsy: 2mg-60mg each day, in divided doses
- To control muscle spasm: 2mg-15mg each day, in divided doses
- To help with control of muscle spasms as in tetanus: the dose you are given will depend upon your bodyweight and will be based upon 3 to 10mg for every kg of your weight, daily.
- Epilepsy: 2mg-60mg per day, in divided doses
- Alcohol withdrawal symptoms: 5mg-20mg, which may be repeated after 2 to 4 hours if necessary
- Before operation: 2mg-20mg

Children and adolescents

- For night terrors and sleep walking: 1mg-5mg before going to bed
- For muscle spasm associated with tetanus, dose depends upon bodyweight - and will usually be 3 to 10mg for every kg of bodyweight, daily
- Spasticity in cerebral palsy: 2mg-40mg each day, in divided doses
- Before operation: 2mg-10mg

Specific patient groups

- **Elderly or frail:** you are likely to be more sensitive to the effects of Diazepam oral solution, especially sedation, drowsiness and confusion. Your doctor will give you much lower doses, this should not be more than half the adult dose.
- **Breathing, liver or kidney problems:** you may be given a lower dose.

If you take more Diazepam oral solution than you should

If you (or someone else) swallow a lot of

Diazepam Oral Solution, 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 drowsiness, clumsiness, and loss of coordination, feeling sleepy or deep sleep, speech problems, irregular or slow heartbeat, uncontrolled eye movement, muscle weakness. An extreme overdose may lead to coma (unrousable unconsciousness), reflex problems and breathing difficulties.

If you forget to take Diazepam oral solution

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 oral solution

- Do not stop taking your medicine without telling your doctor as they may gradually reduce your dose before stopping it completely. If stopped suddenly, you may have unpleasant side effects including headaches, muscle pain, extreme anxiety, tension, restlessness, confusion, diarrhoea and irritability. In severe cases you may experience depersonalisation (feeling that your mind is becoming separated from your body), derealisation (feeling that the world around you is not real), abnormally acute hearing or painful sensitivity to sound, numbness and tingling in arms and legs, over sensitivity to light, noise and physical contact, seeing, hearing or feeling things that are not there (hallucinations) or fits.
- Withdrawal symptoms include depression. Withdrawal symptoms may occur between normal and high doses or if your doctor is switching you to another benzodiazepine.
- Treatment should be gradually withdrawn, otherwise the symptoms being treated may return more intense than before (rebound insomnia and anxiety). Mood changes, anxiety, restlessness or changes in sleep patterns may also occur.

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.

Stop treatment and contact a doctor at once if you have:

- **allergic reaction** e.g. itchy skin, skin redness and swelling and skin rash, sudden wheezing, swelling of the face, lips, tongue, throat or body, rash, fainting or difficulty breathing or swallowing.

- Respiratory depression (very slow and/or shallow breathing) (Uncommon)
- Respiratory arrest (cessation of breathing) (Rare)

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

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 oral solution' 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 (particularly in children)

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

- Mental side effects such as excitation, agitation, restlessness, irritability, aggressiveness, 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 withdrawal, 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 (particularly in children)
- 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)
- Unconsciousness
- Jaundice (yellowing of your skin or the white of your eyes)

Very rare: may affect up to 1 in 10,000 people

- 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)
- Temporary pause in breathing

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 or search for MHRA Yellow Card in the Google Play or Apple App Store. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Diazepam oral solution

Keep out of the sight and reach of children. Do not store above 25°C. Keep container in the outer carton and keep the container tightly closed. Do not take Diazepam oral solution 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. Contents of the pack and other

Information

What Diazepam oral solution contains

- The active substance (the ingredient that makes the oral solution work) is diazepam. Each 5ml spoonful contains 2mg of the active ingredient.
- The other ingredients are docusate sodium, aluminium magnesium silicate, propylene glycol, raspberry flavour, saccharin sodium, erythrosine (E127), sorbic acid (E200), propyl parahydroxybenzoate (E216), methyl parahydroxybenzoate (E218), sorbitol (E420), glycerol (E422).

What Diazepam oral solution looks like and contents of the pack

Diazepam oral solution is a pink syrup with an odour of raspberries.

Pack sizes are 100ml.

Marketing Authorisation Holder and manufacturer:

Accord, Barnstaple, EX32 8NS, UK

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