

Diazepam 2 mg/5 ml Oral Suspension

Read all of this leaflet carefully before you start taking your 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 any of the side effects gets serious, 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 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 belongs to a group of medicines known as benzodiazepines, which have sedative and muscle relaxing properties.

Diazepam Oral Suspension is used to treat a number of conditions including:

In Adults

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

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 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

Do not take Diazepam if you:

- are allergic or sensitive to the active substance, benzodiazepines or any of the ingredients in this medicine (see section 6 Further information).
- are breathless or have difficulty breathing including slow and/or shallow breathing.
- planning a pregnancy or are pregnant (see below 'Pregnancy and breast-feeding')
- have or have ever had any mental illness including depression, phobia, obsession, anxiety, hyperactivity and inability to concentrate.
- have myasthenia gravis (a condition which causes muscles to weaken and tire easily)
- suffer from sleep apnoea (a condition where you stop breathing whilst asleep)
- have severe liver disorders
- have porphyria (an inherited condition causing skin blisters, abdominal pain and brain or nervous system disorders)

Warnings and precautions

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

- have problems with your heart and lungs or have kidney or liver disease
- are elderly or you are weakened by illness.
- have breathing problems
- have suicidal thoughts
- have epilepsy or a history of seizures
- have any disorder of the brain (hardening of the arteries in the brain).
- have problems with your circulation.
- have low blood levels of a protein called albumin
- have depression (with or without anxiety)
- have a personality disorder
- someone close to you has recently died.
- are or have been a user/abuser of alcohol and/or drugs or have a personality disorder (in these circumstances your doctor should monitor you regularly whilst you are taking diazepam and not prescribe further solution unless there are very particular reasons to do so).

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** – there is a risk of dependence, which increases with the dose and duration of treatment if you have a history of alcoholism and drug abuse. Therefore, you should take Diazepam tablet 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 go and see 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'.

You should take the lowest dose possible and you should not continue the treatment beyond 4 weeks

If any of the above apply to you or you are unsure, please talk to your doctor before taking the medicine.

Other medicines and Diazepam Oral Suspension

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),
- sedatives (to calm you down),
- antipsychotics such as clozapine (to treat mental problems),
- antihistamines (to treat allergies),
- general anaesthetics (used during surgery or dental treatment),
- hypnotics (to help you sleep),
- erythromycin (an antibiotic),
- muscle relaxants (eg baclofen, tizanidine, suxamethonium, tubocurarine)
- some strong pain killers 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 e.g. captopril, enalapril or Lisinopril; 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, carbamazepine, or 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.
- 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.
- amprenavir, atazanavir, ritonavir, delavirdine, efavirenz, indinavir, nelfinavir or saquinavir (antivirals) as these can make you feel sleepy for longer or cause difficulty breathing.
- fluconazole, voriconazole, itraconazole or ketoconazole (antifungal 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.
- oestrogen-containing 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 (to treat Parkinson's disease) as diazepam may cause levodopa to not work so well.
- 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),
- neuroleptics (for mental illness) and other medicines for mental illness such as zotepine, tranquilisers (sleeping tablets).
- beta-blockers (e.g. propranolol or atenolol for heart problems)
- HIV-protease inhibitors: (e.g. zidovudine)

Concomitant use of Diazepam 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 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.

If you are going to have an operation involving an anaesthetic, the hospital will need to know in advance that you are taking Diazepam.

Diazepam with food and drink

Do not drink alcohol while you are taking diazepam. Alcohol may increase the sedative effects of Diazepam and make you very sleepy. If you regularly drink alcohol please tell your doctor before using this medicine. 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 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 if you are pregnant or planning to become pregnant. If you take Diazepam late in your pregnancy or during labour your baby might have a low body temperature, floppiness, breathing and feeding difficulties. If you take this medicine regularly during late pregnancy, your baby may develop withdrawal symptoms. Since Diazepam passes in the breast milk, Diazepam should not be given to breast feeding mothers. Ask your doctor or pharmacist for advice before taking this medicine.

Driving and Using machines:

Diazepam may make you feel sleepy, affect your concentration or you may have problems with the way your muscles work.

Do not:

- drive or use any tools or machines if you are affected in this way
- take part in other activities where this would put you at risk

- drink alcohol, as this will make these effects worse. You should make sure that you get enough sleep, otherwise you may experience difficulty staying alert. If this happens do not drive, use tools or operate machines. 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 contains sucrose, Ponceau 4R red (E124), methyl and propyl hydroxybenzoate (E218 and E216) and ethanol If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicine. Also, sucrose may be harmful to the teeth. Diazepam contains the colouring Ponceau 4R red (E124) which may cause allergic reactions.

Diazepam contains methyl and propyl hydroxybenzoate (E218 and E216). These may cause allergic reactions (possibly delayed).

This medicine contains 3.6 mg of alcohol (ethanol) in each 5 ml, which is equivalent to 0.72 mg/ml. The amount in 1 ml of this medicine is equivalent to less than 1 ml beer or 1 ml wine. The small amount of alcohol in this medicine will not have any noticeable effects.

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

3 How to take Diazepam

Always take this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure. You should not take Diazepam for longer than 4 weeks and you should take the lowest dose possible in order to control the illness. Diazepam Oral Suspension should be taken by mouth. Daily doses should be divided and taken on two or three separate occasions during the day, for example in the morning, at midday and at night or as instructed. You should make sure you are able to have 7-8 hours of uninterrupted sleep.

Important: These suspensions should be shaken well before using.

The dose of Diazepam Oral suspension may vary according to the condition being treated and the following is a guide to the doses often used:

Adults

For anxiety: the usual dose is 2mg three times a day, this may be increased up to 30mg daily in divided doses if necessary.

For sleeping difficulties associated with anxiety: 5mg to 15mg before going to bed.

For cerebral palsy and muscle spasms, associated with upper motor neurone disease or muscle spasms associated with epilepsy, fibrositis, cervical spondylosis: your doctor may tell you to take 2mg to 15mg daily in divided doses, up to 60mg in severe cases.

For muscle spasms associated with conditions such as epilepsy, fibrositis, cervical spondylosis: 2mg to 15mg daily 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.

Before a dental operation: the usual dose is 5mg the night before, 5mg on waking and another 5mg two hours before the appointment.

To help with alcohol withdrawal symptoms: your doctor may tell you to take 5mg to 20mg, which may be repeated after 2 to 4 hours if necessary.

Use in children and adolescents:

For night terrors and sleep walking: the usual dose is 1mg to 5mg daily before going to bed. Before an operation: 2mg to 10mg is usual.

To control muscle spasms, as in tetanus: this dose is based on your child's bodyweight and will be between 3 to 10mg for each kg of weight, daily.

For cerebral palsy: 2mg to 40mg daily in divided doses is usual.

Older people

The dosage should be half that recommended for adults above.

If you take more Diazepam than you should:

If you accidentally take too much suspension or you think a child may have swallowed any, immediately seek medical help from your doctor or local casualty department. Signs of overdose include clumsiness, loss of coordination, feeling sleepy or deep sleep, drowsiness, irregular or slow heartbeat, uncontrolled eye movement, muscle weakness, shaky movements, excitement or slurred speech. In very severe cases you may lose consciousness, have breathing difficulties or experience reflex problems.

If you forget to take Diazepam

Do not double the dose in order to make up for a forgotten dose.

If you are at all concerned, you should consult your doctor or pharmacist for advice.

- If you remember within one hour of the missed dose take your medicine now and continue with your next dose at the usual time.
- If your next dose is less than 2 hours away, skip the missed dose and take the next dose now.

If you stop taking Diazepam

Do not stop taking your medicine without telling your doctor as he may wish to gradually reduce the amount you take before stopping it completely. If you stop taking Diazepam suddenly you may experience unpleasant side effects including headaches, muscle pain, extreme anxiety, tension, restlessness, confusion, sleep disturbance, serious mood or behavioural changes, tremors or convulsions. Nervousness, insomnia, irritability, sweating, diarrhoea and depression may also occasionally if your treatment has only been for a short period of time. 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 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.

As with other benzodiazepine drugs, there is the possibility of dependence on treatment occurring, but this normally does not happen with low doses and short courses of treatment. 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.

If you experience the following, stop taking Diazepam Suspension and tell your doctor immediately or go to your nearest hospital.

Stop treatment and contact your doctor immediately if you have the following symptoms of an allergic reaction: rash, itching, swelling of the face, lips, mouth or throat that may cause difficulty in swallowing or breathing.

The following side effects have been reported. If you experience any of these see your doctor at once:

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)

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 (particularly in children)

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

- 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 with suicidal tendencies
- Emotional withdrawal
- Insomnia (problems sleeping)
- Difficulty speaking
- 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)

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

Drinking alcohol may exaggerate these effects.

You could notice the above 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

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 the Yellow Card Scheme (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

- 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 bottle or carton. The expiry date refers to the last day of that month.
- Diazepam Suspension should be stored below 25°C. Please keep in the original carton to protect the medicine from light.
- If you notice any defects with this product such as a non-pink colour you should take this medicine to your pharmacist for advice before taking it.

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 contains

- The active substance is Diazepam. Each 5ml of your medicine contains 2mg diazepam in Diazepam 2mg/5ml Oral Suspension
- The other ingredients are sucrose, microcrystalline cellulose, glycerin, methyl hydroxybenzoate (E218), propyl hydroxybenzoate (E216), ethanol, croscarmellose sodium, framboise (raspberry) flavour, Ponceau 4R red (E124), potassium sorbate and purified water.

What Diazepam looks like and the content of the pack

Diazepam Oral Suspension is a pink, raspberry flavoured suspension. Diazepam is available in bottles supplied in volumes of 50ml, 100ml, 150ml, 250ml, 300ml or 500ml. Not all pack sizes may be marketed.

Marketing Authorisation Holder

Sandoz Limited, Park View, Riverside Way, Watchmoor Park, Camberley, Surrey, GU15 3YL, United Kingdom

Manufacturer:

Sandoz Limited, Park View, Riverside Way, Watchmoor Park, Camberley, Surrey, GU15 3YL, United Kingdom **and/or** PURNA PHARMACEUTICALS NV/SA, Rijksweg 17, B-2870 Puurs

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