Package leaflet: Information for the user
Diazepam 0.4 mg/ml Oral Suspension
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.

The name of your medicine is Diazepam 0.4 mg/ml Oral Suspension but it will be referred to as 'Diazepam' throughout this leaflet.

What is in this leaflet

1. What Diazepam is and what it is used for

Diazepam belongs to a group of medicines called benzodiazepines. Diazepam helps in the treatment of anxiety and muscle spasms.

Adults
Diazepam has tranquilizing, sedative, and muscle relaxant effects.

Diazepam is used to treat anxiety, agitation, and psychic tension caused by psychoneurotic states and transient situational disorders. Diazepam is used for the short-term symptomatic treatment of anxiety that is severe, disabling or subjecting the individual to extreme distress.

Diazepam is also used in the symptomatic treatment of acute alcohol withdrawal syndrome.

Adults and children from 6 months of age
Diazepam contributes to the relief of muscle pain caused by spasms or inflammation of muscles or joints, trauma, etc. It can also be used to combat spasms caused by diseases such as cerebral palsy (a group of disorders that affects a person's ability to move, maintain balance and posture) and paraplegia (paralysis of the lower half of the body, affecting both legs), as well as athetosis (continuous, involuntary, slow, and extravagant movements of fingers and hands) and generalized stiffness syndrome.

You must talk to a doctor if you do not feel better or if you feel worse.

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).

- If you are allergic (hypersensitive) to other medicines in the benzodiazepine group.
- If you suffer from sleep apnoea (a sleep disorder where you have abnormal pauses in breathing during sleep).
- If you have a condition called myasthenia gravis, which is characterized by muscle weakness and tiredness
- If you have severe breathing problems (severe respiratory failure).
- If you have severe liver problems (severe liver failure).

Do not use this medicine in children under 6 months of age.

Warnings and precautions
Talk to your doctor or pharmacist before taking Diazepam:
- If you have breathing difficulties
- If you have a history or problems of dependence on drugs or central nervous system depressants, including alcohol
- If you are taking other medications
- If you have thoughts of suicide

Other considerations
- **Amnesia** - you could experience amnesia when taking this medicine. Amnesia is more likely to occur when taking high doses of diazepam.
- **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.
- **Rebound insomnia -** When you stop taking diazepam you may experience sleeplessness or anxiety. The risk of this is greater if you stop suddenly.
- **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.
- **Psychiatric and Paradoxical Reactions** - Reversible effects such as restlessness, agitation, irritability, aggressive behaviour, nightmares, hallucinations, delusions, rage, inappropriate behaviour and other behavioural disturbances or abnormal mental states (psychosis) may occur with benzodiazepines, particularly in elderly patients or children (see section 4). In such cases, Diazepam solution should be discontinued
- **Concomitant Use of Alcohol/CNS Depressants -** Concomitant use of Diazepam with alcohol and/or CNS depressants should be avoided. Such concomitant use has the potential to increase the clinical effects of Diazepam, including severe sedation that may result in coma or death, respiratory and/or clinically relevant cardiovascular depression

Your doctor will decide whether you should take a lower dose of Diazepam or not at all.

In patients with depression, Diazepam only acts on the anxiety component, so it does not in itself constitute a treatment for depression and may eventually unmask some signs of depression.

If you are epileptic and are on long-term treatment with Diazepam, the use of the benzodiazepine antagonist Anexate (flumazenil) to reverse the effect of Diazepam is not recommended as seizures may occur.

Your doctor will pay special attention to the high risk associated with you if you are elderly or very debilitated.

Risk of dependency
The use of benzodiazepines, and benzodiazepine-type drugs can lead to physical and psychological dependence. This is more likely with higher doses of the medicine, if you have a history of alcohol or drug abuse or if you take the medicine for a long time. To minimize the risk of dependence, the following precautions should be taken into account:

- Benzodiazepines should be taken only under medical prescription.
- Do not increase the doses prescribed by your doctor at all, or prolong treatment longer than recommended.
- See your doctor regularly to decide if you should continue treatment.

Children
The duration of treatment should be as short as possible.

Elderly patients
Elderly patients may need lower doses of Diazepam than younger patients. The pharmacological effects of benzodiazepines in elderly patients appear to be greater than in the younger population.
If you are an elderly patient, your doctor may prescribe a lower dose and check your response to treatment. Please follow your doctor's instructions carefully.

Patients with hepatic disorders
Benzodiazepines may contribute to the precipitation of episodes of hepatic encephalopathy in severe hepatic impairment. Particular caution should be exercised when administering Diazepam to patients with mild to moderate hepatic impairment.

Other Medicines and Diazepam
Tell your doctor or pharmacist if you are taking, have recently taken, or might need to take any other medicine. This is extremely important because the simultaneous use of more than one drug can increase or decrease its effect. For example, tranquilizers, sleep inducers, and similar medications act on the brain and nerves and may increase the effect of Diazepam.

In particular, tell your doctor if you are taking any of the following medicines:

- Cisapride (used to treat stomach problems), cimetidine (stomach acid reducing medicines), ketoconazole, fluconazole, voriconazole (anti-fungal medicines), fluvoxamine (used to treat obsessive-compulsive disorder), fluoxetine (antidepressants), hormonal contraceptives, disulfiram (used to treat alcohol addiction), isoniazid (used to treat tuberculosis, diltiazem (used to treat high blood pressure and angina), idelalisib (for the treatment of relapsed chronic lymphocytic leukemia), modafinil, armodafinil (for the treatment of treat excessive sleepiness caused by narcolepsy), esomeprazole, and omeprazole (stomach acid reducing medicines) temporarily increase the sedative effect of Diazepam, increasing the risk of drowsiness. The same goes for grapefruit juice.

Conversely, medications such as rifampicin (an antibiotic) and carbamazepine (used to treat seizures) produce a decrease in the effects of Diazepam.

Also, phenytoin (used to treat seizures) metabolism may be affected if you are taking Diazepam, so if you are taking this medication, your doctor will adjust the doses of the same.

The sedative effect and cardiorespiratory depression may be increased by combining Diazepam with other Central Nervous System depressants, which may cause coma or death.

The effects of muscle relaxants (suxamethonium, tubocurarine), analgesics and nitrous oxide may be enhanced.

Use of benzodiazepines and opioids increases the risk of sedation, respiratory depression, coma and death.

Combination with antiviral agents (atazanavir, ritonavir, delavirdine, efavirenz, indinavir, nelfinavir, saquinavir) may lead to increased risk of sedation and respiratory depression.

Combination with valproic acid may result in increased blood levels of diazepam.

Chronic use of corticosteroids may lead to reduced effect of diazepam

CYP3A4 and/or CYP2C19 inhibitors may cause increased concentrations of diazepam, medicines such as rifampicin, St. John's Wort, and certain anti-epileptics may lead to decreased plasma concentrations of diazepam.

Xanthines such as theophylline and caffeine oppose the sedative effects of Diazepam.

Therefore, you should not use Diazepam with any other medication, unless you have been allowed to do so by your doctor.

If you need more information about this, ask your doctor or pharmacist.

Diazepam with food, drink and alcohol
Alcoholic beverages increase the sedative effects of Diazepam, so avoid the use of alcoholic beverages during treatment. If you need additional information, consult your doctor. Diazepam should not be taken in combination with grapefruit juice, as grapefruit juice can increase the levels of diazepam in your body.

Food and antacids may slow down, but they will not decrease the absorption of diazepam. This may lead to milder effects after a single dose, but does not affect during treatment with multiple doses.

Prokinetic medications (medications to improve bowel transit) increase the absorption of diazepam.

Pregnancy and breastfeeding
Consult your doctor or pharmacist before using any medicine.

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, due to strict medical requirements, Diazepam is taken before or during childbirth, hypothermia (abnormally low body temperature), weakness, hypotension and breathing difficulties may appear in the newborn. There have also been cases of withdrawal syndrome in newborns.

Benzodiazepines pass into breast milk, therefore you should not take Diazepam while you are breastfeeding

Driving and using machines
Diazepam significantly affects the ability to drive and to operate machines. Do not drive or operate tools or machines because this medication may cause sedation, amnesia, difficulty concentrating, and muscle weakness, which may adversely affect your ability to drive or operate machinery. The doctor must decide when these activities can be resumed. This effect is increased if you have also ingested alcohol.

Diazepam contains:
Methyl parahydroxybenzoate (E218) and propyl parahydroxybenzoate (E216): May cause allergic reactions (possibly delayed).
Sodium: This medicine contains less than 1 mmol sodium (23 mg) per ml, that is to say essentially 'sodium-free'.
Ethanol (E1510): This medicine contains 1 mg of alcohol (ethanol) per ml. The amount in 5 ml dose of this medicine is equivalent to less than 1 ml beer or 1 ml wine. Adults and older children should not experience any effect but effects on younger children are less certain. This medicinal product contains small amounts of ethanol (alcohol), less than 100mg per 5.5 ml.
Sucrose: If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product. This medicine contains 220 mg of sucrose per ml. This should be taken into account in patients with diabetes mellitus. May be harmful to the teeth.
Propylene glycol (E1520): This medicine contains 1.78 mg propylene glycol per ml. If your baby is less than 4 weeks old, talk to your doctor or pharmacist before giving them this medicine, in particular if the baby is given other medicines that contain propylene glycol or alcohol.
Benzoic acid (E210): This medicinal product contains 0.0011mg benzoic acid per ml.

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. Depending on the nature of your illness, your age and weight, your doctor will prescribe the most appropriate dose and indicate the duration of your Diazepam treatment.

Remember to take your medication.

Follow these instructions unless your doctor has given you different instructions:

Adults:
Anxiety symptoms: 2mg (5ml) to 10 mg (25ml), 2 to 3 times a day, depending on the severity of symptoms. Maximum dose is 30 mg (75 ml) per day.

Symptomatic relief in acute alcohol deprivation: 10 mg (25ml), 3 or 4 times during the first 24 hours, reducing to 5 mg (12.5 ml) 3 or 4 times a day, as needed.

Adjuvant for the relief of musculoskeletal spasm: 2mg (5ml) to 10 mg (25ml), 3 or 4 times a day.

Dosage in special populations
Use in children: 0.1 - 0.3 mg/ kg per day, in 2 to 4 divided doses. Benzodiazepines should not be used in children without careful evaluation of the indication. Because of the varying response of children to CNS-acting medications, treatment should be started at the lowest dose and increased as needed.

Do not use in children under 6 months of age.

In the elderly or in the presence of debilitating diseases: 2mg (5ml) to 2.5 mg (6.25ml), 1 or 2 times a day, then gradually increasing, according to need and tolerance

Treatment should be started with the lowest dose. Do not exceed the maximum dose.

If you think that the action of Diazepam is too strong or weak, tell your doctor or pharmacist.

In elderly patients or those who suffer from a liver or kidney disorder, or muscle weakness, in children, in weakened patients or who have a low serum albumin level, the doctor will prescribe a lower dose.

Rules for correct administration
Do not increase, in any way, the doses prescribed by the doctor.

Each individual dose should not exceed the indicated limits and neither should the total daily dose, unless your doctor prescribes a higher dose.

Diazepam can be taken at the times they are most necessary, normally in the afternoon or evening. Never change the dose that has been prescribed for you yourself.

It is important that you use the correct device to measure your dose. Your doctor or pharmacist will let you know which device to use depending on the dose that has been prescribed.

1ml oral dosing syringe	**10 ml oral dosing syringe**	**25 ml measuring cup**
The 1ml syringe has black graduations in steps of 0.01 ml. If the required dose is 1 ml or less, you should use the 1 ml oral syringe and the adaptor provided in this pack If the required dose is more than 1 ml, you should use the 10ml syringe or 25 ml measuring cup provided.	The 10 ml oral syringe has black graduations in steps of 0.1 ml. If the required dose is between 1 ml and 10 ml, you should use the 10 ml oral syringe and the adaptor provided in this pack. If the required dose is more than 10 ml, you will need to use the 25 ml measuring cup provided.	The 25 ml measuring cup has graduations in steps of 2.5 ml. If the required dose is above 10 ml, you should use the 25 ml measuring cup provided.

Duration of treatment
The duration of treatment should be as short as possible and never longer than 4 weeks. Consult your doctor regularly to decide whether treatment should be continued.

Do not prolong treatment longer than recommended.

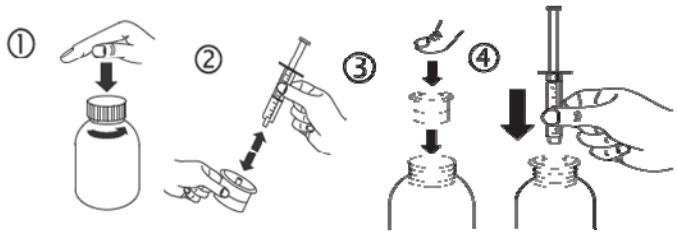
To avoid withdrawal symptoms, you should not stop taking Diazepam suddenly, especially if you have been taking it for a long time.

Route and method of administration
- This medicine must be taken orally.
- Use the measuring syringes or cup provided in the pack to deliver the required dose.
- Shake well before use for at least 10 seconds.

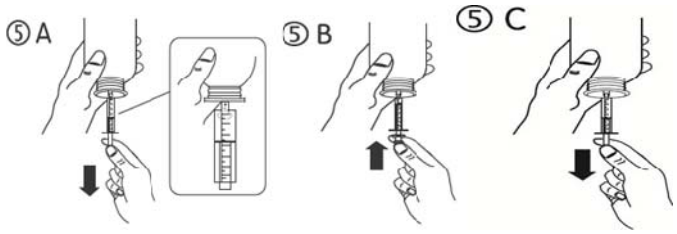
Instructions for the use of syringe:

a) Open the bottle: press the cap and turn it anticlockwise (figure 1).

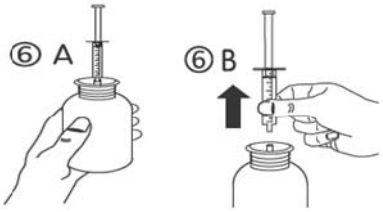
b) Separate the adaptor from the syringe (figure 2). Insert the adaptor into the bottle neck (figure 3). Ensure it is properly fixed. Take the syringe and put it in the adaptor opening (figure 4).



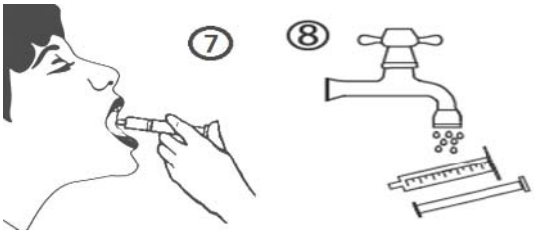
c) Turn the bottle upside down. Fill the syringe with a small amount of suspension by pulling the piston down (figure 5A) and then push the piston up in order to remove any possible air bubbles (figure 5B). Pull the piston down to the graduation mark corresponding to the quantity in millilitres (ml) prescribed by your doctor (figure 5C).



d) Turn the bottle the right way up (figure 6A). Remove the syringe from the adaptor (figure 6B).



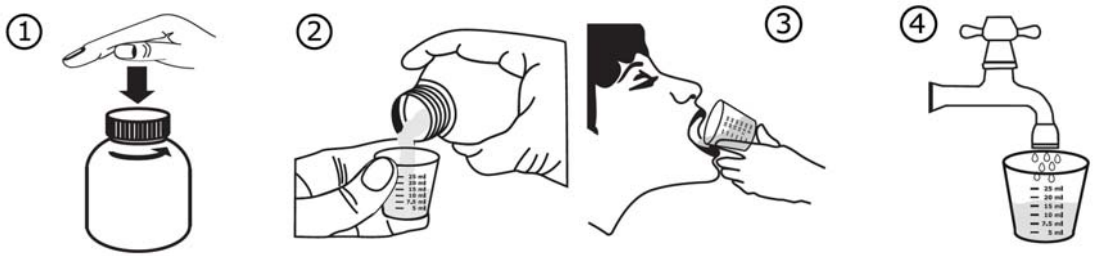
e) Empty the contents of the syringe into the mouth by pushing the piston to the bottom of the syringe (figure 7). The contents of the syringe should be emptied into the side cheek of the patient's mouth to avoid a choking hazard. Close the bottle with the plastic screw cap. Wash the syringe with water (figure 8).



Instructions for the use of cup:

a) Open the bottle: press the cap and turn it anticlockwise (figure 1).

b) Fill the cup with a small amount of suspension by tilting the bottle horizontally to the graduation mark corresponding to the quantity in millilitres (ml) prescribed by your doctor (figure 2).
c) Empty the contents of the cup into the patient's mouth slowly to avoid a choking hazard (figure 3).
d) Close the bottle with the plastic screw cap. Wash the cup with water (figure 4).



If you take more Diazepam than you should
If you (or someone else) swallow a lot of Diazepam, 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. Severe overdose can lead to central circulatory and respiratory depression (cyanosis, loss of consciousness leading to respiratory failure, cardiac arrest) and coma.

If you forget to take Diazepam
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
- do not stop taking your medicine without telling your doctor as they may gradually reduce your dose before stopping it completely.
- Restlessness, anxiety, insomnia, lack of concentration, headache and hot flashes may occur when you stop taking Diazepam. It is generally not recommended to abruptly stop the medication but rather to gradually reduce the dose, according to the doctor's instructions.
- 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.

Most patients tolerate Diazepam well but the most common adverse effects, which occur especially at the beginning of treatment, are fatigue, muscle weakness and drowsiness.

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)
- respiratory arrest (cessation of breathing).
- restlessness, disorientation, agitation, irritability, delirium (incoherence of ideas), attacks of anger, aggression, nervousness, hostility, anxiety, nightmares, abnormal dreams, hallucinations, psychosis (loss of contact with reality), hyperactivity or inappropriate behaviour (more common in children and the elderly).

Other adverse effects such as confusion, decreased alertness, loss of sensitivity, dizziness, affective disorders, emotional and mood disturbances, constipation, depression, diplopia (double vision), ataxia (inability to coordinate movements) have occasionally been described. voluntary muscle movements), difficulty in articulating words, digestive disturbances, altered heart rate, headache, hypotension, circulatory disturbances, changes in libido (sexual desire), nausea, dry mouth or hypersalivation (exaggerated salivary secretion), incontinence or urinary retention, skin rashes, babbling, tremor, vertigo and blurred vision. The most common skin reactions are rash (inflammation of the skin), urticaria (reddish welts), and pruritus (uncomfortable tingling or irritation of the skin that causes the desire to scratch the affected area).

Increased transaminases and alkaline phosphatase, jaundice (yellowing of the skin and eyes), as well as cardiac arrest have been reported very rarely.

An increased risk of falls and fractures has been observed in elderly patients and in patients who are concurrently taking other sedative medications (including alcoholic beverages). Heart failure, respiratory depression, including respiratory failure may occur.

You may become dependent on diazepam or similar medicines (physical or psychological dependence).

If you suddenly stop taking diazepam, you may suffer withdrawal symptoms. These include extreme anxiety, tension, restlessness, confusion, irritability, headaches and muscle pain. In severe cases you may feel out of touch with reality, feel strange in familiar surroundings, have hallucinations, have numbness and tingling sensation in your arms and legs, become over-sensitive to light, noise and physical contact or have epileptic seizures.

When you stop taking diazepam you may experience difficulty sleeping (rebound insomnia).

Anterograde amnesia (difficulty remembering recent events) may occur at normal doses, the risk increases when the dose is increased. Amnestic effects may be associated with behavioural alterations.

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 Website: www.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.
- Do not use this medicine after the expiry date which is stated on the carton and bottle label after EXP. The expiry date refers to the last day of that month
- Store below 25°C.
- Do not refrigerate or freeze
- Discard 30 days after first opening.
- Do not use this medicine if you notice that the suspension becomes discoloured or shows any signs of deterioration. Seek the advice of your pharmacist.
- Do not throw away any medicine 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 ml of oral suspension contains 0.4 mg of diazepam.
The other ingredients are: methyl parahydroxybenzoate (E218), propyl parahydroxybenzoate (E216), simethicone emulsion (contains benzoic acid (E210), polysorbate 80 (E433), potassium sorbate (E202), glycerol (E422), microcrystalline cellulose and carmellose sodium, ethanol (96%) (E1510), erythrosine (E127), sucrose, raspberry flavour (contains propylene glycol (E1520)) and purified water.

What Diazepam looks like and contents of the pack
Diazepam is a pink oral suspension in a glass bottle. Each pack contains one bottle containing 100 ml oral suspension.

The pack also contains a 1ml syringe with 0.01 ml intermediate graduation, a 10 ml syringe with 0.1 ml intermediate graduation, bottle adaptor and a 25 ml measuring cup with 2.5 ml intermediate graduation

Marketing Authorisation Holder:
Syri Pharma Limited t/a Thame Laboratories
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Manufacturer:
Pharmadox Healthcare Ltd.
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This medicine is authorised in the Member States of the European Economic Area under the following name:
NL: Diazepam Syri Pharma 0.4 mg/ml, suspensie voor oraal gebruik
IE: Diazepam 0.4 mg/ml Oral Suspension

This leaflet was last revised in 10/2025.