

PACKAGE LEAFLET: INFORMATION FOR THE USER

Diazepam Injection 10mg/2ml

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 or nurse.
- 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 or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet:

1. **What Diazepam Injection 10mg/2ml is and what it is used for**
2. **What you need to know before you are given Diazepam Injection 10mg/2ml**
3. **How to take Diazepam Injection 10mg/2ml**
4. **Possible side effects**
5. **How to store Diazepam Injection 10mg/2ml**
6. **Contents of the pack and other information**

1. WHAT DIAZEPAM INJECTION 10MG/2ML IS AND WHAT IT IS USED FOR

Diazepam Injection 10mg/2ml contains a medicine called diazepam. It belongs to a group of medicines called benzodiazepines.

It is used:

- in the short-term treatment of anxiety and agitation that is severe, disabling or associated with unacceptable distress
- for the control of muscle spasms including tetanus
- for the treatment of convulsions with fever (e.g febrile conditions) and as a result of poisoning
- in the treatment of some forms of epilepsy (e.g status epilepticus)
- as premedication prior to and as sedative cover during surgery and minor surgical procedures
- in the short term treatment of anxiety and agitation due to alcohol withdrawal (delirium tremens) that is severe.

2. WHAT YOU NEED TO KNOW BEFORE YOU ARE GIVEN DIAZEPAM INJECTION 10MG/2ML

You should not be given Diazepam Injection 10mg/2ml if you:

- are allergic to diazepam, other benzodiazepines or any of the other ingredients in this medicine (listed in section 6)
- have a phobia (a fear of a particular object or situation), obsessions, a personality disorder or other mental illness
- have difficulty in breathing, are short of breath or have weakness of your chest muscles that help you breathe (including a condition called Myasthenia Gravis)
- have 'sleep apnoea syndrome' a condition where your breathing stops for short spells when you are asleep
- have severe liver problems
- have Porphyria, a disorder of the blood
- are planning a pregnancy or are pregnant (see section pregnancy and breast-feeding).

Warnings and precautions:

This medicine will be given under the supervision of a doctor or nurse.

Talk to your doctor before you are given Diazepam Injection 10mg/2ml:

- if you suffer from depression (with or without anxiety)
- if you are elderly
- if you have a kidney, liver, heart or lung condition
- if you have breathing problems
- if you have epilepsy or a history of seizures
- if you have a history of alcohol or drug abuse or dependence
- if someone close to you has recently died
- if you have suicidal thoughts
- if you have had changes in your brain, particularly arteriosclerosis (a narrowing of the blood vessels).

When given intravenously, Diazepam Injection 10mg/2ml can slow down your breathing and heart rate. On rare occasions this has caused breathing or the heart to stop. To avoid this, doses are given slowly and are as low as possible.

Other medicines and Diazepam Injection 10mg/2ml

Tell your doctor or nurse if you are using or have recently used or might use any other medicines, including medicines obtained without a prescription.

- Amnesia** - you could experience amnesia when taking this medicine. Amnesia is more likely to occur when taking high doses of medicine, including medicines obtained without a prescription, especially:
- **antidepressants** (e.g. fluvoxamine, fluoxetine)
 - **antipsychotics** such as clozapine (to treat mental problems)
 - **antihistamines** (for the treatment of allergies)
 - **general anaesthetics**
 - **sedatives** (used to give calming effects)
 - **erythromycin** (an antibiotic)
 - **suxamethonium**, (e.g. tubocurarine)
 - some **strong pain killers** such as **morphine** (opioids) may give you a heightened sense of well-being when taken with diazepam which can increase your desire to continue taking these medications (dependency) or can make you very sleepy
 - barbiturates such as **phenobarbital** (used to treat epilepsy and mental disorders)
 - medicines to **lower high blood pressure, diuretics** (water tablets), **nitrate** (for heart conditions) as

these could lower your blood pressure too much

- **antacids** (to reduce 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 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
- **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), **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. As these can make you feel sleepy for longer or cause difficulty breathing
- **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 Injection 10mg/2ml with food, drink and alcohol

Do not drink alcohol if you are being given Diazepam Injection 10mg/2ml. Alcohol may increase the sedative effects of Diazepam Injection 10mg/2ml 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 Injection 10mg/2ml and you should speak to your doctor, pharmacist or nurse.

Drinks containing **caffeine** may reduce the effects of diazepam.

Pregnancy and breast-feeding:

Do not take this medicine if you are pregnant, might become pregnant, or are breast-feeding. If your doctor has decided that you should receive this medicine during late pregnancy or during labour, your baby might have a low body temperature, floppiness, breathing and feeding difficulties.

Infants born to mothers who receive this medicine for a **prolonged** period during **late** pregnancy may develop **dependence** and be at risk of withdrawal symptoms **after** birth.

Infants born to mothers who receive this medicine during the **first three months** of pregnancy **may** be at increased **risk** of **deformities** being present at birth. Please tell your **doctor or nurse** before being given this injection if you are **breast-feeding** - if possible this injection should be **avoided** during breast-feeding.

Driving and using machines:

Diazepam may cause drowsiness, blurring of vision, unsteadiness and loss of alertness, you should not drive or operate any machinery during treatment, particularly if you notice any of these effects.

Details regarding a **new driving offence** concerning driving after drugs have been taken in the UK may be found here: <https://www.gov.uk/drug-driving-law>

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 Injection 10mg/2ml contains benzyl alcohol, benzoic acid, sodium benzoate and dehydrated alcohol

This medicine contains 15mg/ml of benzyl alcohol. This medicine must not be given to premature babies or neonates. It may cause toxic reactions and allergic reactions in infants and in children up to 3 years old.

This medicine also contains 1mg/ml of benzoic acid and 49mg/ml of sodium benzoate. This may increase the risk of jaundice in newborn babies.

This medicinal product contains less than 1 mmol sodium (23 mg) per dose, i.e. essentially 'sodium-free'.

This medicinal product contains 12.5 vol % ethanol (alcohol) i.e. 100mg per ml, equivalent to 10ml beer, 4ml wine per dose. It is therefore harmful to those suffering from alcoholism. This should also be taken into account in pregnant or breast-feeding women, children and high risk groups such as patients with liver disease or epilepsy.

3. HOW TO USE DIAZEPAM INJECTION 10MG/2ML

This medicine will be given to you by a doctor or nurse.

The dose of Diazepam Injection 10mg/2ml may vary according to the condition being treated and the following is a guide to the doses usually given:

Adults:

Severe acute anxiety or agitation: 10mg by intramuscular injection (i.m.) or intravenous injection (i.v.) which may be repeated after a minimum period of 4 hours.

Alcohol withdrawal symptoms (delirium tremens): 10mg to 20mg by i.v. or i.m. injection. If the symptoms are very severe a higher dose may be given.

Acute muscle spasms: 10mg by i.m. or i.v. injection which may be repeated after a minimum period of 4 hours.

Tetanus: In this case the dose will depend on body weight and is usually based on 0.1-0.3mg/kg weight and the dose is repeated at intervals of 1 to 4 hours. In very severe cases, your doctor may decide a higher dose is appropriate.

Epilepsy and for convulsions due to poisoning: 10mg to 20mg by i.v. or i.m. injection and repeated if necessary 30-60 minutes later.

As premedication: The dose will depend on body weight and is based on 0.2mg/kg body weight. The usual adult dose will be 10-20mg but higher doses may sometimes be given.

Elderly or debilitated patients:

The dose is usually not more than half that recommended for a healthy adult.

Children:

Epilepsy, convulsions due to poisoning and feverish conditions: 0.2mg to 0.3mg/kg body weight by i.v. or i.m. injection. Alternatively, the dose may be based on 1mg per year of life.

Tetanus: The dose is the same as that recommended for adults.

As premedication: The dose is based on 0.2mg/kg body weight.

Your doctor may decide to change your dose according to your condition. Ask your doctor if you want more information. In usual circumstances, your course of treatment with diazepam should not be longer than four weeks.

If you are given more Diazepam Injection 10mg/2ml than you should: Overdose by this medicine is unlikely since treatment is carefully monitored.

Stopping treatment with Diazepam Injection 10mg/2ml:

Treatment with this medicine will be tapered off gradually. If you have been treated with benzodiazepines for a long time this tapering off may be for a long period.

Sudden withdrawal of diazepam, particularly if you have been given large doses, may produce confusion, serious mood or behavioural changes, tremors or convulsions.

Patients on long-term treatment may become dependent upon this medicine. After long-term treatment the following withdrawal symptoms may occur: headache, muscle pain, anxiety, restlessness, confusion, irritability, inability to sleep, hallucinations (seeing and hearing things that are not there) and convulsions. Your doctor will advise you on how to reduce your dose gradually to avoid these effects happening to you.

4. POSSIBLE SIDE EFFECTS

Like all medicines, this medicine can cause side effects, although not everyone 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: 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 'Long term

treatment' below)

- Confusion
- Loss of coordination of muscle movements (ataxia) and other movement disorders, tremor.

Uncommon: may affect up to 1 to 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 swelling and skin rash.

Rare: may affect up to 1 to 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
- Decreased alertness
- Depression
- Numbing of your emotions (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)
- Blood disorders (you may develop sore throats, nose bleeds or infections)
- Difficulty speaking.

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

- Low levels of white blood cells (leukopenia)
- Reduction in the number of certain types of blood cells (Thrombocytopenia)
- 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)
- Sensation that you, or the environment around you, is moving or spinning (vertigo)
- Breathing difficulties (apnoea)
- Injection site pain or redness
- Swelling and redness of veins
- Blood clots
- Worsening of lung disease
- Metabolic disorders.

Long term treatment: Patients who receive long term treatment with diazepam may become tolerant (their medicine becomes less effective) or dependent upon their medicine.

After treatment for a long time (such as in an intensive care unit) the following withdrawal symptoms may occur: headaches, muscle pain, anxiety, restlessness, confusion, irritability, inability to sleep, hallucinations and convulsions.

Your doctor will reduce your dose gradually to avoid these effects happening to you.

If you think this injection is causing you **any problems**, or you are at all worried, **talk to your doctor, pharmacist or nurse.**

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

By reporting side effects you can help provide more information on the safety of this medicine.

5. HOW TO STORE DIAZEPAM INJECTION 10MG/2ML

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

This medicine will be given by a doctor or nurse.

Do not use this medicine after the expiry date which is stated on the label and carton. The expiry date refers to the last day of that month. Store below 25°C and protect from light.

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 Injection 10mg/2ml contains:

This medicine contains the active substance diazepam.

Each ampoule contains 10mg of diazepam in 2ml of solution.

The other ingredients are: benzoic acid, dehydrated alcohol, propylene glycol, sodium benzoate, benzyl alcohol and water.

What Diazepam Injection 10mg/2ml looks like and contents of the pack:

Diazepam Injection 10mg/2ml is a colourless to light yellow solution for injection.

Diazepam Injection 10mg/2ml are packed into boxes of 10 ampoules.

Marketing Authorisation Holder:

Ennogen Pharma Limited
Unit G4, Riverside Industrial Estate,
Riverside Way, Dartford, DA1 5BS, UK.

Manufacturer:

Human Serum Production & Medicine
Manufacturing Co Limited
H-2100 Godollo, Tancsics Mihály UT 82
Budapest, Hungary

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