

1.4.3. PATIENT INFORMATION LEAFLET (PIL)

VERZEPAM
Diazepam Injection BP, 5mg/ml-2ml

Read all of this leaflet carefully before you start using 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, pharmacist or nurse.
- If you get any side effects, talk to your doctor 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 BP is and what it is used for
2. What you need to know before you are given Diazepam Injection BP
3. How Diazepam Injection BP is given
4. Possible side effects
5. How to store Diazepam Injection BP
6. Contents of the pack and other information.

1. What Diazepam Injection BP is and what it is used for

Diazepam belongs to a group of medicines called benzodiazepines. It can cause you to fall asleep and it can also have a calming effect.

Diazepam can be given by injection into a vein (intravenously), by a drip (infusion) or injection into a muscle (intramuscular). This medicine is used in adults and children for sedation during investigations and treatment.

It is also used as a premedication to calm patients before treatment and to sedate patients in intensive care units.

Diazepam is used as an anti-convulsant to treat epileptic seizures and to control muscle spasms as in tetanus. It is also used in the management of alcohol withdrawal syndromes.

2. What you need to know before you are given Diazepam Injection BP

You should NOT be given Diazepam Injection BP:

- If you are allergic to diazepam, the group of medicines known as benzodiazepines or any of the other ingredients (listed in section 6) in this injection.
- If you have a phobia (a fear of a particular object or situation), obsessions, a personality disorder or other mental illness.
- if you have difficulty in breathing, are short of breath or have weakness of your chest muscles that help you breath (including a condition called Myasthenia Gravis).
- If you have “Sleep Apnoea Syndrome” - a condition where your breathing stops for short spells when you are asleep.
- If you have Porphyria - a disorder of the blood.
- If you have a liver condition.
- If you are planning a pregnancy or are pregnant (see Pregnancy and breast-feeding below).

Warnings and precautions

Talk to your doctor, pharmacist or nurse before receiving Diazepam Injection BP:

- If you suffer from depression (with or without anxiety).
- If you are over 60 years of age.
- 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 BP 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 BP:

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.

Tell your doctor or pharmacist 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 medicines, 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).
- Muscle relaxants (e.g. suxamethonium, 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), nitrates (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 (antiviral), 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 with drink and alcohol:

Do not drink alcohol if you are being given Diazepam Injection BP. Alcohol may increase the sedative effects of Diazepam Injection BP 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 BP and you should speak to your doctor, nurse or pharmacist. Drinks containing **caffeine** may reduce the effects of diazepam.

Pregnancy and breast-feeding:

You should not be given Diazepam Injection BP if you are pregnant, planning to become pregnant or are breast feeding.

If your doctor decides you should be given this medicine during late pregnancy, labour or caesarean section, your baby might have an irregular heart beat, a low body temperature, floppiness and 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:

This medicine may make you sleepy, forgetful or affect your concentration and coordination. This may affect your performance at skilled tasks, e.g. driving or operating machinery. Your doctor should advise you when you can start these again.

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

3. How Diazepam Injection BP is given

Your doctor, nurse or dentist will give you the injection.

Your doctor, nurse or dentist will decide the correct dosage for you and how and when the injection will be given.

If you are given more Diazepam Injection BP than you should

Since the injection will be given to you by a doctor, nurse or dentist, it is unlikely that you will be given too much. If you think you have been given too much you must tell the person giving you the injection

4. Possible side effects

Like all medicines, Diazepam Injection BP can cause side effects, although not everybody 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: affects 1 to 10 users in 1,000

- Respiratory depression (very slow and/or shallow breathing)

Rare: affects 1 to 10 users in 10,000

- Respiratory arrest (cessation of breathing)
- Unconsciousness
- Jaundice (yellowing of your skin or the white of your eyes)

Very rare: affects less than 1 user in 10,000

- 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: affects more than 1 user in 10

- Drowsiness

Common: affects 1 to 10 users in 100

- 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: affects 1 to 10 users in 1,000

- 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: affects 1 to 10 users in 10,000

- 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
- 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)

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)

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, nurse or pharmacist.

5. How to store Diazepam Injection BP

Keep this medicine out of the sight and reach of children. Store at a temperature not exceeding 30°C. protected from light.

6. Contents of the pack and other information

What Diazepam Injection BP contains:

The active substance is diazepam. In Diazepam Injection BP each 1 ml of solution contains 5 mg of diazepam.

The other ingredients are:

Benzyl Alcohol

Propylene Glycol

Ethyl Alcohol

Disodium EDTA

Sodium Benzoate

Benzoic Acid

Water for Injections

What Diazepam Injection BP looks like and contents of the pack:

A Clear, colourless to light yellowish solution filled in 2 ml amber glass ampoules.

2ml

10 x 2 ml amber red ring ampoule USP type -1 IHS loaded on a plastic tray.

10 x 2 ml tray loaded amber red ring ampoules in an inner printed carton.

10 x 10 x 2 ml amber red ring ampoules in an outer printed carton.

MARKETING AUTHORISATION HOLDER AND MANUFACTURING SITE ADDRESSES

Marketing Authorisation Holder

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