

Diazepam Injection BP

Important information about your medicine

- ▶ Your doctor or nurse will give you the injection
- ▶ If this injection causes you any problems talk to your doctor, nurse or pharmacist
- ▶ Please tell your doctor or pharmacist, if you have any other medical conditions or have an allergy to any of the ingredients of this medicine
- ▶ Please tell your doctor or pharmacist, if you are taking any other medicines

- **Read all of this leaflet carefully** before you start using this medicine. In some circumstances **this may not be possible** and this leaflet will be kept in a safe place should you wish to read it.
- **Keep this leaflet.** You may need to read it again
- If you have any further questions, please **ask your doctor or your pharmacist.**
- This medicine has been prescribed for you personally and you should not pass it on to others. It may harm them, even if their symptoms are the same as yours.

Where to find information in this leaflet

1. What Diazepam Injection BP is and what it is used for
2. Before you are given Diazepam Injection BP
3. How to use Diazepam Injection BP
4. Possible side effects
5. Storing Diazepam Injection BP
6. Further 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. Before you are given Diazepam Injection BP

You should NOT be given Diazepam Injection BP if you:

- are **sensitive** or **allergic** to the group of medicines known as benzodiazepines or any of the other ingredients of Diazepam Injection BP.
- 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**).
- You have "**Sleep Apnoea Syndrome**" - a condition where your breathing stops for short spells when you are asleep.
- You have a **liver** condition.

Please tell your doctor or nurse before being given the injection if you:

- are over 60 years of age.
- have a **kidney** or **heart** condition.
- have a history of **alcohol** or **drug abuse**.
- have a **marked personality disorder**.
- have **Porphyria** - a disorder of the blood.
- 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.

Using other medicines:

Please tell your doctor or nurse if you are taking or have recently taken any other medicines, including medicines obtained without a prescription. This is especially important with the following medicines as they may interact with your Diazepam Injection BP.

- **Tranquillisers** or **Sedatives**
- **Hypnotics** (sleep inducing drugs)
- **Antidepressants**
- **Narcotic** analgesics (very strong pain killers)
- **Antiepileptics** (for treating epilepsy)
- **Anaesthetics**
- Some **antihistamines** (for the treatment of allergies)
- **Levodopa** - a medicine for Parkinson's Disease
- **Theophylline** - a medicine to help you breathe
- **Sodium Oxybate** - a medicine to help you stay awake
- **Antibiotics** (erythromycin & rifampicin)

The effects of diazepam may also be increased by medicines such as:

- Disulfiram - used to treat alcohol dependency
- Drugs used to treat blood pressure
- Drugs used to treat digestive problems
- Some drugs used to treat HIV and AIDS
- Baclofen and tizanidine (used to relax your muscles)

Alcohol may increase the sedative effects of diazepam and should therefore be **avoided**. Do not drink alcohol until your doctor tells you it is all right to do so.

Pregnancy or breast feeding:

Please tell your **doctor, dentist or nurse** before being given this injection if you are **pregnant**. The doctor will then decide if the injection is suitable for you.

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.

You should **always** be **accompanied home** by a responsible **adult** after your treatment.

3. How to use Diazepam Injection BP

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

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

Since the injection will be given to you by a dentist, doctor or nurse, 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.

- **Immune system disorders:** hypersensitivity reactions including **anaphylaxis** (a severe and rapid allergic reaction) where you may experience low blood pressure, breathing difficulties, feeling sick, itchiness, swelling of the lips, face, neck and throat.

If you have **any** of these symptoms, or you are at all worried, tell your doctor, nurse or pharmacist **immediately**.

- **Skin disorders:** rash, itchiness, allergic reaction

- **Nervous system disorders:** drowsiness and prolonged sedation, reduced alertness, confusion, euphoria (an excessive feeling of wellbeing), hallucinations, tiredness, headache, dizziness and difficulty coordinating muscles

- **Temporary memory loss** has been reported. How long this lasts will depend on how much diazepam you were given and you may experience this after your treatment. In isolated cases this has been prolonged.

- **Reactions** such as agitation, muscle spasms and muscle tremors, restlessness, hostility, rages and aggression, have been reported.

Other reactions include depression, numbing of your emotions, changes in your appetite and libido and ideas of suicide.

Paradoxical (not typical or expected) reactions include difficulty in sleeping, nightmares, sexual arousal and inappropriate behaviour.

Children and the elderly are more susceptible to these reactions.

- **Dependence on Diazepam** after **prolonged** intravenous use. It is important that you are withdrawn from your medicine gradually to avoid withdrawal symptoms, including withdrawal convulsions

- **Gastrointestinal disorders:** feeling sick, dry mouth

- **Heart and breathing disorders:** Events include low blood pressure, breathing complications, shortness of breath, blockage of airway.

- **The elderly** may be more susceptible to the adverse effects of Diazepam.

- **Blood disorders:** You may have reduced numbers of, and changes to, certain types of your blood cells.

- **Liver disorders:** changes in the **chemicals** in your **blood** made by the liver and **jaundice** (your skin and the whites of your eyes may develop a **yellow** tinge).

- **Injection site disorders:** redness and pain, swelling and redness of veins, blood clots.

- **Other disorders:** including **visual** disturbances, weakness in your **muscles**, difficulty to hold or pass **urine**.

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. Storing Diazepam Injection BP

Your injection will be stored in a cool place and protected from light. The nurse or doctor will check that the injection is not past its expiry date before giving you the injection.

6. Further information

What Diazepam Injection BP contains:

This injection contains the **active ingredient** Diazepam. Each 1 ml of solution contains 5 mg of Diazepam.

This injection contains the following **inactive ingredients:** ethanol, propylene glycol, sodium hydroxide, water for injections.

This medicinal product contains **0.04 mg sodium per ml**. This should be taken into consideration for patients on a **controlled sodium diet**.

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

Diazepam Injection BP is a clear, colourless, sterile solution contained in clear glass ampoules.

The injection is available in packs of 10 ampoules containing 2 ml of solution.

The marketing authorisation number of this medicine is: PL 01502/0025

Marketing Authorisation Holder:

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Manufacturer:

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For any information about this medicine, please contact the Marketing Authorisation Holder

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