Diazepam Injection BP

diazepam

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

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

of alcohol withdrawal syndromes.

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.

- (see Pregnancy and breast-feeding below).

before receiving Diazepam Injection BP:

- anxiety).
- if you have a kidney, liver, heart or lung condition.
- · if you have breathing problems.
- · if you have a history of alcohol or drug abuse or
- if someone close to you has recently died.
- if you have had changes in your brain, particularly arteriosclerosis (a narrowing of the blood vessels).

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

Concomitant use of diazepam and opioids (strong

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 However if your doctor does prescribe diazepam together with opioids the dose and duration of

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

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

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

- prescription, especially:
- antidepressants (e.g. fluvoxamine, fluoxetine). • antipsychotics such as clozapine (to treat mental problems).
- · general anaesthetics. sedatives calming aive
- (used effects).
- erythromycin (an antibiotic). muscle
- some strong pain killers such as morphine (opioids) may give you a heightened sense of
- 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)

affect your mental status, make you very sleepy and suppress your breathing and blood pressure. · disulfiram (to treat alcohol addiction). Taking this

Taking these medicines with diazepam could

- 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,
- and phenytoin carbamazepine, 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 itraconazole, fluconazole, (antivirals), 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
- 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 edative effects of Diazepam Injection BP ar 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.

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

Pregnancy and breast-feeding:

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

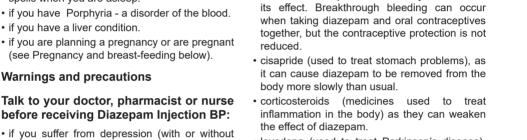
affect your concentration and coordination. This

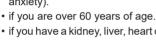
may affect your performance at skilled tasks, e.g. driving or operating machinery. Your doctor should advise you when you can start these again. You should always be accompanied home by a responsible adult after your treatment.

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





dependence.

- · if you have epilepsy or a history of seizures.
- · if you have suicidal thoughts.
- When given intravenously, Diazepam Injection BP

pain killers, medicines for substitution therapy and some cough medicines) increases the risk of

concomitant treatment should be limited by your

inform friends or relatives to be aware of the signs

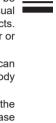
a prescription.

- · antihistamines (for the treatment of allergies).
- relaxants (e.g. suxamethonium, tubocurarine).
- well-being when taken with diazepam which can increase your desire to continue taking these
- as these could lower your blood pressure too

· antacids (to reduce stomach acid) may slow

down absorption of diazepam in the body.





- 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

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

- · Withdrawal symptoms (for possible symptoms please see 'Long term treatment', below.
- · 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, delusion, rages, psychoses, memory loss. 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 (bradycardia), heart failure and cessation of
- heartbeat (cardiac arrest) · Low blood pressure, fainting (syncope)

slow heartbeat

- · 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

After treatment for a long time (such as in an intensive care unit) the following withdrawal symptoms may occur: headaches, muscle pain, 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.

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 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 Injection BP

Keep this medicine out of the sight and reach of

Your injection will be stored at less than 25°C and protected from light.

Do not use this medicine after the expiry date which is stated on the label/ carton after "EXP:" The expiry date refers to the last day of that month.

6. Contents of the pack and other <u>information</u>

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 ethanol, propylene glycol, sodium hydroxide and 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:

hameln pharma Itd Nexus, Gloucester Business Park, Gloucester, GL3 4AG United Kingdom

Manufacturer:

Siegfried Hameln GmbH Langes Feld 13 31789 Hameln Germany

Horná 36 900 01 Modra Slovak Republic

hameln rds s.r.o.

Sklabinská 30 03680 Martin Slovak Republic

HBM Pharma s.r.o.

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

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