

DBL™ Diazepam Injection

Diazepam (dye-AZ-eh-pam)

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about DBL Diazepam Injection.

It does not contain all the available information.

It does not take the place of talking to your doctor or pharmacist.

All medicines have risks and benefits. Your doctor has weighed the risks of you being given DBL Diazepam Injection against the benefits they expect it will have for you.

If you have any concerns about this medicine, ask your doctor or pharmacist.

Keep this leaflet in a safe place. You may need to read it again.

What DBL Diazepam Injection is used for

Diazepam belongs to a group of medicines known as benzodiazepines (*ben-zo-dye-AZ-eh-peens*).

These medicines appear to have their effect by acting on certain areas of the brain.

Diazepam has sedative and muscle relaxant effects. It is used for a number of conditions, including:

- tension and anxiety
- repeated or prolonged epileptic seizures (convulsions/fits)
- to help relax you before an operation (preoperative medication)
- muscle spasm

- for the relief of symptoms of alcohol withdrawal
- muscle stiffness due to cerebral palsy or paraplegia.

Your doctor may have prescribed diazepam for another reason. Ask your doctor if you have any questions about why DBL Diazepam Injection has been prescribed for you.

In general, medicines such as DBL Diazepam Injection should be taken for short periods only (for example 2 - 4 weeks). Continuous long term use is not recommended unless advised by your doctor. The use of this medicine may lead to dependence on diazepam.

This means you may experience unpleasant feelings if you stop taking this medicine suddenly. However, it is also important to treat your condition. Your doctor will be able to advise you on how to prevent and manage this.

This medicine is available only with a doctor's prescription.

Before you are given DBL™ Diazepam Injection

When you must not be given it

You should not be given DBL Diazepam Injection if you have an allergy to diazepam or any other medicine in the benzodiazepine group or any of the ingredients listed at the end of this leaflet.

Symptoms of an allergic reaction to diazepam may include:

- shortness of breath, wheezing or difficulty breathing
- swelling of the face, lips, tongue or other parts of the body
- rash, itching or hives on the skin.

You should not be given DBL Diazepam Injection if:

- you have a breathing disorder, known as severe or chronic obstructive airways disease, or with respiratory failure.
- you have depression, psychosis or schizophrenia that is not being treated.
- you have myasthenia gravis, a condition in which the muscles become weak and tire easily.

DBL™ Diazepam Injection should not be given to people with medical shock, coma, poor heart and lung function or alcohol intoxication.

This medicine should not be given to you after the expiry date (EXP) printed on the pack.

If you are given this medicine after the expiry date has passed, it may not work as well.

DBL Diazepam Injection should not be given to you if the packaging is torn or shows signs of tampering.

If you are not sure whether you should be given diazepam talk to your doctor or pharmacist.

Before you are given it

Tell your doctor or pharmacist if you have allergies to:

- any other medicines
- any other substances, such as foods, preservatives or dyes.

Tell your doctor or pharmacist if you are pregnant or intend to become pregnant.

Your doctor or pharmacist will discuss the risks and benefits of you being given diazepam during pregnancy.

Tell your doctor or pharmacist if you are breast-feeding or plan to breast-feed.

DBL Diazepam may pass into the breast milk and cause drowsiness and/or feeding difficulties in the baby.

It is not recommended for use while breastfeeding.

Tell your doctor or pharmacist if you have or have had any medical conditions, especially the following:

- glaucoma
- lung, kidney or liver problems
- depressed mood or other mental illness such as schizophrenia
- previous drug or alcohol addiction problems
- high or low blood pressure
- fits or convulsions (epilepsy).

Tell your doctor or pharmacist if you drink alcohol regularly. Do not drink alcohol while you are given diazepam.

Alcohol may increase the effects of diazepam

If you have not told your doctor or pharmacist about any of the above, tell them before you are given DBL Diazepam Injection.

Taking other medicines

Tell your doctor or pharmacist if you are taking/using any other medicines, including any that you buy without a prescription from your pharmacy, supermarket or health food shop.

Some medicines and diazepam may interfere with each other. These include:

- disulfiram, a medicine used to treat alcohol dependency
- levodopa, a medicine used in the management of Parkinson's disease

- isoniazid, rifampicin, clarithromycin or erythromycin, medicines used to treat some bacterial infections
- ketoconazole or fluconazole, medicines used to treat fungal infections
- ritonavir, a medicine used to treat HIV/AIDS
- some medicines used to treat depression (e.g. amitriptyline, fluoxetine, fluvoxamine)
- some medicines used to reduce stomach acid or treat stomach ulcers such as esomeprazole, cimetidine and omeprazole
- anticholinergics (e.g. atropine) which may be taken for stomach cramps
- some medicines used to treat anxiety, mental illness with disordered thinking (e.g. clozapine, remoxipride, olanzapine)
- some medicines for epilepsy/fitting (e.g. sodium valproate, phenytoin, carbamazepine)
- antihistamines
- strong pain relievers or opioids (e.g. ketamine, methadone, morphine, fentanyl, oxycodone or codeine)
- alcohol
- sedatives and sleeping tablets
- other medicines which may make you feel drowsy
- muscle relaxants and anaesthetics
- combined oral contraceptives
- diltiazem, a medicine used to treat heart disease
- idelalisib, verapamil, medicines used to treat blood cancer
- modafinil or armodafinil, medicines used to treat sleepiness

These medicines may be affected by diazepam, or may affect how well it works. You may need different amounts of your medicine, or you may need to use different

medicines. Your doctor or pharmacist will advise you.

Grapefruit juice has also been found to interfere with diazepam. You should avoid drinking grapefruit juice when you are receiving this medicine.

Your doctor and pharmacist may have more information on medicines to be careful with or avoid while you are being given Diazepam Injection.

How DBL Diazepam Injection is given

How much is given

Your doctor will decide what dose you will receive. This depends on your condition.

How it is given

DBL Diazepam Injection is usually given as a slow injection into a vein (intravenously). It can also be given as an injection into a muscle.

DBL™ Diazepam Injection should only be given by a doctor, nurse or other trained person.

How long it is given for

DBL Diazepam Injection should only be given for short periods of 2 to 4 weeks. Your doctor will decide how long you will receive this medicine for.

If you take too much (overdose)

This rarely happens as DBL Diazepam Injection is administered under the care of a highly trained doctor or nurse. Your condition will be carefully monitored following administration.

However, if you are given too much DBL Diazepam Injection you may feel extreme drowsiness, confusion and muscle weakness.

Your doctor or pharmacist has information on how to recognise and treat an overdose. Equipment is available to treat you if you experience severe side effects.

If you think you have been given too much DBL Diazepam Injection or if you experience severe side effects, tell your doctor, pharmacist or nurse immediately.

You may need urgent medical attention.

While you are being given DBL Diazepam Injection

Things you must not do

Do not take any other medicines, whether they are prescription or over-the-counter medicines, unless they have been approved or recommended by a doctor or pharmacist that knows you are being given DBL Diazepam Injection.

Things to be careful of

Be careful driving or operating machinery until you know how diazepam affects you.

Diazepam may cause dizziness, light-headedness, drowsiness and disorientation in some people. It can also affect memory.

If you feel light-headed, dizzy or weak when getting out of bed or standing up, get up slowly.

Standing up slowly will help your body get used to the change in position and blood pressure. If this problem continues or gets worse, talk to your doctor.

Additional precaution should be taken by elderly or unwell patients in order to reduce the risk of a fall.

If you drink alcohol, dizziness and/or drowsiness may be worse.

Following long-term use of diazepam, the medicine may not be as effective as it used to be.

Your doctor may want to gradually reduce the amount of diazepam you have been receiving, before stopping it completely. Suddenly stopping this medicine after long term use or high doses, may cause unwanted side effects.

Side effects

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are being given DBL Diazepam Injection or after the injection.

This medicine may have unwanted side effects in a few people. All medicines can have side effects. Sometimes they are serious, most of the time they are not. You may need medical treatment if you get some of the side effects.

If you are over 65 years of age you may have an increased chance of getting side effects.

Ask your doctor or pharmacist to answer any questions you may have.

Do not be alarmed by this list of possible side effects.

You may not experience any of them.

Tell your doctor or pharmacist if you notice any of the following:

- fatigue
- drowsiness
- lack of coordination
- dizziness
- headache
- light headedness
- fainting
- loss of memory
- inattentiveness
- confusion
- lack of concentration
- rash (hives)
- scaly itchy skin
- blisters on skin
- depressed mood
- dryness of the mouth
- double vision

- difficulty speaking/slurred speech
- fever
- pain, swelling and redness at the injection site
- palpitations (irregular heart beat)
- muscle problems
- difficulty urinating
- nausea, vomiting, diarrhoea or constipation
- unpleasant dreams

These are the more common side effects of this medicine.

Tell your doctor immediately or go to Accident and Emergency at your nearest hospital if you notice any of the following:

- breathing difficulties, choking or coughing
- fast breathing
- fast or irregular heart beat
- allergic reaction symptoms as described near the start of this leaflet
- sudden anxiety or excitation
- behavioural problems such as rage, anger
- restlessness
- agitation
- irritability
- hallucinations or delusions (seeing or hearing things that are not there)
- abnormal behaviour
- severe sleep disturbances
- unusual bleeding or bruising
- yellowing of the skin or eyes (jaundice)

These are serious side effects. You may need urgent medical attention. Serious side effects are rare.

Other side effects not listed above may occur in some patients. Tell your doctor or pharmacist if you notice anything that is making you feel unwell.

After being given DBL™ Diazepam Injection

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Storage

DBL Diazepam Injection should be stored in a cool dry place, protected from light, where the temperature stays below 25°C.

Disposal

If your doctor tells you to stop using DBL Diazepam Injection, or the ampoules have passed their expiry date, ask your pharmacist what to do with any that are left over.

Product description

What it looks like

DBL Diazepam Injection is a clear, colourless to pale yellow liquid in a glass ampoule.

Ingredients

Active ingredients:

- Each ampoule contains 10 mg of diazepam per 2 mL

Other ingredients

- propylene glycol
- ethanol absolute
- water for injections
- Sodium hydroxide

DBL Diazepam Injection does not contain lactose, sucrose, gluten, tartrazine or any other azo dyes.

Supplier / Sponsor

DBL Diazepam Injection is supplied by:

Australian Sponsor:

Pfizer Australia Pty Ltd
Sydney NSW
Toll Free Number: 1800 675 229
www.pfizer.com.au

DBL™ Diazepam Injection is available in the following strength:
10 mg/2 mL AUST R 115049