

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 severe breathing disorder, known as chronic obstructive airways disease (COAD), with lung 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.

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

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

- if you are not breathing properly or have a breathing disorder known as chronic obstructive airways disease (COAD) with lung failure
- glaucoma
- kidney or liver problems
- muscular disorders, such as myasthenia gravis
- depressed mood or other mental illness such as schizophrenia
- previous drug 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 taking 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 and rifampicin, medicines used to treat some infections
- ketoconazole, a medicine used to treat fungal infections
- some medicines used to treat depression (eg. amitriptyline, fluoxetine, fluvoxamine)
- some medicines used to treat stomach ulcers such as cimetidine and omeprazole
- anticholinergics (eg atropine) which may be taken for stomach cramps
- some medicines used to treat mental illness with disordered thinking (eg clozapine, remoxipride)
- some medicines for epilepsy/fitting (eg sodium valproate, phenytoin)
- antihistamines
- strong pain relievers or opioids (eg methadone, morphine, fentanyl, oxycodone or codeine)
- alcohol
- sedatives and sleeping tablets
- other medicines which may make you feel drowsy
- muscle relaxants and anaesthetics

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.

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)

Your doctor or pharmacist has information on how to recognise and treat an overdose. Symptoms of a diazepam overdose may include extreme drowsiness, confusion and muscle weakness.

If you experience any of the above symptoms tell your doctor, pharmacist or nurse immediately

Immediately telephone your doctor or the Poisons Information Centre (telephone 13 11 26 in Australia, or call 0800 764 766 in New Zealand) for advice, or go to Accident and Emergency at the nearest hospital, if you think that you or anyone else may have taken too much DBL™ Diazepam Injection. Do this even if there are no signs of discomfort or poisoning. You may need urgent medical attention.

While you are being given DBL™ Diazepam Injection

Things you must do

Tell any other doctors, dentists, and pharmacists who are treating you that you have been given DBL™ Diazepam Injection.

If you are about to be started on any new medicine, tell your doctor, dentist or pharmacist that you are being given DBL™ Diazepam Injection.

If you plan to have surgery that needs a general anaesthetic, tell your doctor or dentist that you are being given DBL™ Diazepam Injection.

If you become pregnant while you are being given DBL™ Diazepam Injection, tell your doctor or pharmacist.

Things you must not do

Do not give DBL™ Diazepam Injection to anyone else, even if they have the same condition as you.

Do not use DBL™ Diazepam Injection to treat any other complaints unless your doctor or pharmacist tells you to.

Do not stop using DBL™ Diazepam Injection, or lower the dosage, without checking with your doctor or pharmacist.

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.

Make sure you know how you react to DBL™ Diazepam Injection before you drive a car, operate machinery, or do anything else that could be dangerous if you are dizzy or drowsy. If this occurs do not drive.

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

Be careful if you are elderly or unwell.

Some people may experience side effects such as drowsiness, confusion, dizziness and unsteadiness, which may increase the risk of a fall.

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
- rash (hives)
- 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

These are the more common side effects of this medicine.

Tell your doctor immediately or go to a casualty at your nearest hospital if you notice any of the following:

- breathing difficulties
- allergic reaction symptoms as described near the start of this leaflet
- behavioural problems such as rage, anger or hallucinations (seeing or hearing things that are not there)
- 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

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 vial.

Ingredients

Active ingredients:

- Each ampoule contains 10 mg of diazepam per 2 mL

Other ingredients

- propylene glycol
- ethanol absolute
- water for injections

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:

Hospira Australia Pty Ltd
ABN 58 097 064 330
Level 3
500 Collins Street
Melbourne VIC 3000
Australia

New Zealand Sponsor:

Pfizer New Zealand Limited
PO Box 3998
Auckland, New Zealand
Toll Free Number: 0800 736 363

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

This leaflet was prepared in September 2017.