

DBL™ Diazepam Injection

Consumer Medicine Information (CMI) summary

The [full CMI](#) on the next page has more details. If you are worried about using this medicine, speak to your doctor or pharmacist.

1. Why am I being treated with DBL Diazepam Injection?

DBL Diazepam Injection contains the active ingredient diazepam. DBL Diazepam Injection is used for a number of conditions including: tension and anxiety, repeated or prolonged epileptic seizures, to help relax you before an operation, muscle spasm, for the relief of symptoms of alcohol withdrawal, and muscle stiffness due to cerebral palsy or paraplegia.

For more information, see Section [1. Why am I being treated with DBL Diazepam Injection?](#) in the full CMI.

2. What should I know before treatment with DBL Diazepam Injection?

Do not start treatment if you have ever had an allergic reaction to DBL Diazepam Injection, or any medicine in the benzodiazepine group, or any of the ingredients listed at the end of the CMI.

Talk to your doctor if you have any other medical conditions, take any other medicines, or are pregnant or plan to become pregnant or are breastfeeding.

For more information, see Section [2. What should I know before treatment with DBL Diazepam Injection?](#) in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with DBL Diazepam Injection and affect how it works.

A list of these medicines is in Section [3. What if I am taking other medicines?](#) in the full CMI.

4. How is DBL Diazepam Injection given?

Your doctor will decide how much DBL Diazepam Injection you will receive. This depends on your condition. DBL Diazepam Injection should only be given by a doctor, nurse, or other trained person.

More instructions can be found in Section [4. How is DBL Diazepam Injection given?](#) in the full CMI.

5. What should I know during treatment with DBL Diazepam Injection?

Things you should do	<ul style="list-style-type: none">● Remind any doctor, nurse, dentist, or pharmacist who is treating you that you are using DBL Diazepam Injection.
Things you should not do	<ul style="list-style-type: none">● Do not stop treatment with this medicine suddenly without speaking to your doctor. Your doctor may want to gradually reduce the amount of diazepam you have been receiving, before stopping it completely.
Driving or using machines	<ul style="list-style-type: none">● Be careful before you drive or use any machines or tools until you know how DBL Diazepam Injection affects you.● Diazepam may cause dizziness,

	lightheadedness, drowsiness and disorientation in some people.
Drinking alcohol	<ul style="list-style-type: none"> • Do not drink alcohol while you are given diazepam. • If you drink alcohol, dizziness and/or drowsiness may be worse.

For more information, see Section [5. What should I know during treatment with DBL Diazepam Injection?](#) in the full CMI.

6. Are there any side effects?

Common side effects include: fatigue, drowsiness, lack of coordination, dizziness, headache, light headedness, fainting, loss of memory, inattentiveness, confusion, lack of concentration, skin problems, 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, stomach problems, unpleasant dreams.

Serious side effects include: breathing difficulties, choking or coughing, fast breathing, fast or irregular heart beat, allergic reaction symptoms, sudden anxiety or excitation, behavioural problems, restlessness, agitation, irritability, hallucinations or delusions,

abnormal behaviour, severe sleep disturbances, unusual bleeding or bruising, yellowing of the skin or eyes.

For more information, including what to do if you have any side effects, see Section [6. Are there any side effects?](#) in the full CMI.

DBL™ Diazepam Injection

Active ingredient(s): *diazepam* (dye-AZ-eh-pam)

Consumer Medicine Information (CMI)

This leaflet provides important information about using DBL Diazepam Injection. **You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about using DBL Diazepam Injection.**

Where to find information in this leaflet:

- [1. Why am I being treated with DBL Diazepam Injection?](#)
- [2. What should I know before treatment with DBL Diazepam Injection?](#)
- [3. What if I am taking other medicines?](#)
- [4. How is DBL Diazepam Injection given?](#)
- [5. What should I know during treatment with DBL Diazepam Injection?](#)
- [6. Are there any side effects?](#)
- [7. Product details](#)

1. Why am I being treated with DBL Diazepam Injection?

DBL Diazepam Injection contains the active ingredient diazepam. DBL Diazepam Injection 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.

DBL Diazepam Injection 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 used 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 using 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.

2. What should I know before treatment with DBL Diazepam Injection?

Warnings

You must not be given DBL Diazepam Injection if:

- you are allergic 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 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.

Always check the ingredients to make sure you can use this medicine.

- 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.
- you are in a medical shock, coma, or have poor heart and lung function or alcohol intoxication.
- the expiry date (EXP) printed on the pack has passed.

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

- 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.

Check with your doctor if you:

- have any allergies to:
 - any other medicines
 - any other substances, such as foods, preservatives or dyes.
- have or have had any other 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).
- take any medicines for any other condition.

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

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them. See additional information under Section [6. Are there any side effects?](#)

Pregnancy and breastfeeding

Check with your doctor if you are pregnant or intend to become pregnant.

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

Talk to your doctor if you are breastfeeding or intend to breastfeed.

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

It is not recommended for use while breastfeeding.

3. What if I am taking other medicines?

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

Some medicines and DBL Diazepam Injection may interfere with each other and affect how they work.

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, verapamil, medicines used to treat heart disease
- idelalisib, a medicine 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 DBL Diazepam Injection.

Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect DBL Diazepam Injection.

4. How is DBL Diazepam Injection 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 are given too much DBL Diazepam Injection

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 that you have been given too much DBL Diazepam Injection, you may need urgent medical attention.

You should immediately:

- contact your doctor, or
- phone the Poisons Information Centre (**by calling 13 11 26**), or
- go to the Emergency Department at your nearest hospital.

You should do this even if there are no signs of discomfort or poisoning.

5. What should I know during treatment with DBL Diazepam Injection?

Things you should do

- Remind any doctor, nurse, dentist or pharmacist who is treating you that you are using DBL Diazepam Injection.

Things you should not do

- Do not stop treatment with this medicine suddenly without speaking to your doctor.

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.

- 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.

Driving or using machines

Be careful before you drive or use any machines or tools until you know how DBL Diazepam Injection affects you.

Diazepam may cause dizziness, lightheadedness, 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 to reduce the risk of a fall.

Drinking alcohol

Tell your doctor if you drink alcohol regularly.

Do not drink alcohol while you are given diazepam.

Alcohol may increase the effects of diazepam.

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

6. Are there any side effects?

All medicines can have side effects. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention.

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

See the information below and, if you need to, ask your doctor or pharmacist if you have any further questions about side effects.

Common side effects

Common side effects	What to do
<p>General disorders and administration site conditions</p> <ul style="list-style-type: none">• fatigue• pain, swelling and redness at the injection site• fever <p>Nervous system</p> <ul style="list-style-type: none">• drowsiness• lack of coordination• dizziness• headache	<p>Speak to your doctor if you have any of these common side effects.</p>

Common side effects	What to do
<ul style="list-style-type: none"> ● light headedness ● fainting ● loss of memory ● confusion ● difficulty speaking/ slurred speech <p>Skin related issues</p> <ul style="list-style-type: none"> ● rash (hives) ● scaly itchy skin ● blisters on skin <p>Changes in behaviour, thinking or mood</p> <ul style="list-style-type: none"> ● depressed mood ● inattentiveness ● lack of concentration ● unpleasant dreams <p>Eye issues</p> <ul style="list-style-type: none"> ● double vision <p>Muscle related issues</p> <ul style="list-style-type: none"> ● muscle problems <p>Renal and urinary related issues</p> <ul style="list-style-type: none"> ● dryness of the mouth ● difficulty urinating <p>Heart related issues</p>	

Common side effects	What to do
<ul style="list-style-type: none"> • palpitations (irregular heart beat) <p>Stomach related issues</p> <ul style="list-style-type: none"> • nausea, vomiting, diarrhoea or constipation 	

Serious side effects

Serious side effects	What to do
<p>Respiratory issues</p> <ul style="list-style-type: none"> • breathing difficulties, choking or coughing • fast breathing <p>Heart related issues</p> <ul style="list-style-type: none"> • fast or irregular heart beat <p>Allergic reaction symptoms</p> <ul style="list-style-type: none"> • 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 	<p>Call your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you notice any of these serious side effects.</p> <p>You may need urgent medical attention.</p> <p>Serious side effects are rare</p>

Serious side effects	What to do
<p data-bbox="204 259 721 367">Changes in behaviour, thinking or mood</p> <ul data-bbox="204 398 730 1267" style="list-style-type: none"> <li data-bbox="204 398 632 506">● sudden anxiety or excitement <li data-bbox="204 524 711 631">● behavioural problems such as rage, anger <li data-bbox="204 649 517 703">● restlessness <li data-bbox="204 721 430 775">● agitation <li data-bbox="204 792 440 846">● irritability <li data-bbox="204 864 730 1079">● hallucinations or delusions (seeing or hearing things that are not there) <li data-bbox="204 1097 676 1151">● abnormal behaviour <li data-bbox="204 1169 523 1267">● severe sleep disturbances <p data-bbox="204 1290 676 1344">Blood related issues</p> <ul data-bbox="204 1375 673 1482" style="list-style-type: none"> <li data-bbox="204 1375 673 1482">● unusual bleeding or bruising <p data-bbox="204 1505 654 1559">Liver related issues</p> <ul data-bbox="204 1590 740 1697" style="list-style-type: none"> <li data-bbox="204 1590 740 1697">● yellowing of the skin or eyes (jaundice) 	

Tell your doctor or pharmacist if you notice anything else that may be making you feel unwell.

Other side effects not listed here may occur in some people.

Reporting side effects

After you have received medical advice for any side effects you experience, you can report side effects to the Therapeutic Goods Administration online at www.tga.gov.au/reporting-problems. By reporting side effects, you can help provide more information on the safety of this medicine.

Always make sure you speak to your doctor or pharmacist before you decide to stop treatment with any of your medicines.

7. Product details

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

What DBL Diazepam Injection contains

Active ingredient (main ingredient)	diazepam
Other ingredients (inactive ingredients)	propylene glycol ethanol water for injections sodium hydroxide

Each ampoule contains 10 mg of diazepam per 2 mL.

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

Do not use this medicine if you are allergic to any of these ingredients.

What DBL Diazepam Injection looks like

DBL Diazepam Injection is a clear, colourless to pale yellow liquid in a glass ampoule. (Aust R 115049).

DBL Diazepam Injection is available in the following strength:

- 10 mg/2 mL

How is DBL Diazepam Injection stored

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

Who distributes DBL Diazepam Injection

Pfizer Australia Pty Ltd

Sydney NSW

Toll Free number: 1800 675 229

www.pfizermedinfo.com.au

This leaflet was prepared in November 2021.

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