

# DIAZEPAM ELIXIR®

Diazepam 10mg/10mL

## 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 using Diazepam Elixir®?

Diazepam Elixir® contains the active ingredient diazepam. Diazepam Elixir® is used for anxiety, to relax muscles, to treat trembling, confusional states or anxiety associated with alcohol withdrawal. It is also used to treat panic attacks.

For more information, see Section [1. Why am I using Diazepam Elixir®?](#) in the full CMI.

### 2. What should I know before I use Diazepam Elixir®?

Do not use if you have ever had an allergic reaction to Diazepam Elixir®, any other benzodiazepine medicine, or any of the ingredients listed at the end of the CMI.

**Talk to your doctor if you have any other medical conditions, have drug or alcohol addiction, drink alcohol, 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 I use Diazepam Elixir®?](#) in the full CMI.

### 3. What if I am taking other medicines?

Some medicines may interfere with Diazepam Elixir® 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 do I use Diazepam Elixir®?

Follow all directions given to you by your doctor or pharmacist carefully. Your doctor or pharmacist will tell you how much Diazepam Elixir® you will need to take each day. This depends on your condition and whether or not you are taking any other medicines.

More instructions can be found in Section [4. How do I use Diazepam Elixir®?](#) in the full CMI.

### 5. What should I know while using Diazepam Elixir®?

<b>Things you should do</b>	Use Diazepam Elixir® exactly as your doctor has prescribed. Remind any doctor, dentist or pharmacist you visit that you are using Diazepam Elixir®. If you become pregnant while you are taking Diazepam Elixir® tell your doctor immediately. Keep enough Diazepam Elixir® to last weekends and holidays.
<b>Things you should not do</b>	Do not take Diazepam Elixir® for a longer period of time than your doctor has prescribed. Do not stop taking Diazepam Elixir® or lower the dose, without first checking with your doctor, especially if you have epilepsy.
<b>Driving or using machines</b>	Be careful before you drive or use any machines until you know how Diazepam Elixir® affects you.
<b>Drinking alcohol</b>	Alcohol may increase the effects of Diazepam Elixir®. Your doctor may suggest that you avoid alcohol or reduce the amount of alcohol you drink while you are taking Diazepam Elixir®.
<b>Looking after your medicine</b>	Keep Diazepam Elixir® in a cool dry place, away from moisture, heat or sunlight, where the temperature stays below 25°C. Keep it where children cannot reach it.

For more information, see Section [5. What should I know while using Diazepam Elixir®?](#) in the full CMI.

### 6. Are there any side effects?

*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:* sudden anxiety or excitation, restlessness, agitation, irritability, anger, hallucinations or delusions, severe sleep disturbances, difficulties in breathing or choking or coughing, or yellowing of the skin and/or eyes (jaundice).

*Speak to your doctor if you have any of these less serious side effects and they worry you:* tiredness, drowsiness, dizziness, unsteadiness, loss of memory, inattentiveness, confusion, lack of concentration, headache, hangover feeling in the morning, slurred speech or unpleasant dreams.

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.

# Diazepam Elixir<sup>®</sup>

Active ingredient: Diazepam 10mg/10mL

## Consumer Medicine Information (CMI)

This leaflet provides important information about using Diazepam Elixir<sup>®</sup>. **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 Diazepam Elixir<sup>®</sup>.**

Where to find information in this leaflet:

- [1. Why am I using Diazepam Elixir<sup>®</sup>?](#)
- [2. What should I know before I use Diazepam Elixir<sup>®</sup>?](#)
- [3. What if I am taking other medicines?](#)
- [4. How do I use Diazepam Elixir<sup>®</sup>?](#)
- [5. What should I know while using Diazepam Elixir<sup>®</sup>?](#)
- [6. Are there any side effects?](#)
- [7. Product details](#)

## 1. Why am I using Diazepam Elixir<sup>®</sup>?

Diazepam Elixir<sup>®</sup> contains the active ingredient diazepam.

Diazepam is used for anxiety. Anxiety or tension associated with the normal stress of everyday life usually does not require treatment with medicines.

Diazepam is used to relax muscles.

Diazepam can also be used to treat trembling, confusional states or anxiety associated with alcohol withdrawal. It is also used to treat panic attacks.

Your doctor, however, may have prescribed Diazepam Elixir<sup>®</sup> for another purpose. Ask your doctor if you have any questions about why Diazepam Elixir<sup>®</sup> has been prescribed for you.

Diazepam Elixir<sup>®</sup> belongs to a group of medicines called benzodiazepines. They are thought to work by their action on brain chemicals.

In general, benzodiazepines such as Diazepam Elixir<sup>®</sup> 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 benzodiazepines may lead to dependence on the medicine.

## 2. What should I know before I use Diazepam Elixir<sup>®</sup>?

### Warnings

**Do not use Diazepam Elixir<sup>®</sup> if:**

- You have an allergy to:

- Diazepam or any of the ingredients listed at the end of this leaflet.
- Any other medicine from the benzodiazepine group of medicines.

Some of the 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.

- You have severe and chronic lung disease.
- You suffer from severe muscle weakness known as myasthenia gravis.
- You suffer from severe liver disease.
- You have temporary stops breathing during sleep.
- You have drug or alcohol addiction (unless being used to treat symptoms of alcohol withdrawal).

### Check with your doctor if you:

- You have allergies to:
  - any other medicines
  - any other substances, such as foods, preservatives or dyes.
- You have or have had any other health problems including:
  - Liver, kidney or lung disease.
  - If you suffer from fits or convulsions.
  - If you have low blood pressure.
  - If you have glaucoma (high pressure in the eye).
  - If you suffer from depression, psychosis or schizophrenia.

If you have not told your doctor about any of the above, tell them before you take any Diazepam Elixir<sup>®</sup>.

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

Do not use Diazepam Elixir<sup>®</sup> if you are pregnant or plan to become pregnant.

It is not known whether Diazepam Elixir<sup>®</sup> is harmful to an unborn baby when taken by a pregnant woman. If there is a need to take Diazepam Elixir<sup>®</sup> when you are pregnant your doctor will discuss the risks and benefits to you and the unborn baby.

**Do not use Diazepam Elixir<sup>®</sup> if you are breastfeeding or plan to breastfeed, unless you and your doctor have discussed the risks and benefits involved.**

Diazepam may pass into the breastmilk and cause drowsiness and/or feeding difficulties in the infant.

**Do not give this medicine to children under 6 months of age, unless advised by the child's doctor.**

**The safety and effectiveness of Diazepam Elixir® in children under 6 months of age has not been established.**

### **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 may interfere with Diazepam Elixir® and affect how it works.** These include:

- other sleeping tablets, sedatives or tranquillisers
- medicines for depression
- medicines for allergies or colds e.g. antihistamines or cold tablets
- pain relievers
- muscle relaxants
- medicines to control fits
- cimetidine and omeprazole: a medicine used to treat gastric reflux and ulcers
- disulfiram, a medicine used to treat alcohol abuse
- cisapride, a medicine used to treat gastric reflux
- ketoconazole, a medicine used to treat fungal infections
- antibiotics, medicine used to treat infections e.g. erythromycin

These medicines may be affected by Diazepam Elixir® or may affect how well Diazepam Elixir® works. You may need to take different amounts of your medicine, or you may need to take different medicines. Your doctor or pharmacist has more information on medicines to be careful with or avoid while taking Diazepam Elixir®.

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

### **4. How do I use Diazepam Elixir®?**

Follow all directions given to you by your doctor or pharmacist carefully. They may differ from the information contained in this leaflet.

#### **How much to take:**

Take Diazepam Elixir® exactly as your doctor has prescribed. Your doctor will tell you how much Diazepam Elixir® to take each day.

The dose of Diazepam Elixir® may be different for each person depending on age and the condition being treated.

The usual adult dose is between 5mg (5mL) and 40mg (40mL) daily. Children, elderly and very ill patients may need to take less.

#### **How to take it:**

Measure out the dose, decided for you by your doctor using a medicine glass and drink all of it, straight away.

#### **When to take it:**

Take Diazepam Elixir® at about the same time each day.

Taking Diazepam Elixir® at the same time each day will have the best effect. It will also help you remember when to take it. Usually it is taken three times daily. It does not matter if you take Diazepam Elixir® before or after food.

#### **How long to take it:**

Do not use Diazepam Elixir® for longer than your doctor says.

Usually Diazepam Elixir® 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 benzodiazepines may lead to dependence on the medicine.

Follow the instructions provided and use Diazepam Elixir® until your doctor tells you to stop.

#### **If you forget to take Diazepam Elixir®**

If it is almost time for your next dose, skip the dose you missed and take your next dose when you are meant to. Otherwise, take it as soon as you remember, and then go back to taking it as you would normally.

Do not use a double dose to make up for the dose that you missed.

If you are unsure whether to take your next dose, speak to your doctor or pharmacist.

If you have trouble remembering to take your medicine, ask your pharmacist for some hints.

#### **If you use too much Diazepam Elixir®**

If you think that you have used too much Diazepam Elixir®, you may need urgent medical attention.

#### **You should immediately:**

- phone the Poisons Information Centre (**by calling 13 11 26**), or

- contact your doctor, or
- go to the Emergency Department at your nearest hospital.

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

Also report any other medicine or alcohol which has been taken.

If you take too much Diazepam Elixir® you may feel drowsy, confused, tired, and dizzy, have difficulty breathing, feel weak or become unconscious.

## 5. What should I know while using Diazepam Elixir®?

### Things you should do

**Use Diazepam Elixir® exactly as your doctor has prescribed.**

**Remind any doctor, dentist or pharmacist you visit that you are using Diazepam Elixir®.**

**If you become pregnant while you are taking Diazepam Elixir® tell your doctor immediately.**

**Tell your doctor or pharmacist that you are taking Diazepam Elixir® if you are about to be started on any new medicines.**

**Tell your doctor if you feel Diazepam Elixir® is not helping your condition.**

**Visit your doctor regularly.** Your doctor needs to check your progress and see whether you need to keep taking Diazepam Elixir®.

**Always discuss with your doctor any problems or difficulties during or after taking Diazepam Elixir®. Tell your doctor if, for any reason, you have not taken your medicine exactly as prescribed.** Otherwise your doctor may think that it was not effective and change your treatment unnecessarily.

**Keep enough Diazepam Elixir® to last weekends and holidays.**

**If you are being treated for anxiety, be sure to discuss with your doctor any problems you may have and how you feel, especially if your anxiety attacks are getting worse or more frequent.** This will help your doctor to determine the best treatment for you.

### Things you should not do

Even if you take Diazepam Elixir® at night, you may still be drowsy or dizzy the next day.

Do not take Diazepam Elixir® for a longer period of time than your doctor has prescribed. Diazepam Elixir® should be taken for short periods only (for example 2 to 4 weeks), unless advised otherwise by your doctor.

Do not stop taking Diazepam Elixir® or lower the dose, without first checking with your doctor.

Stopping this medicine suddenly may cause some unwanted effects. Your doctor will explain how you

should slowly reduce your dose before you can stop using Diazepam Elixir® completely.

Do not suddenly stop taking Diazepam Elixir® if you suffer from epilepsy. Stopping this medicine suddenly may make your epilepsy worse.

Do not use this medicine to treat any other complaints unless your doctor says to.

Do not give Diazepam Elixir® to anyone else, even if their symptoms seem similar to yours.

### Things to be careful of:

Be careful if you are elderly, unwell or taking other medicines.

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

### Driving or using machines

**Be careful before you drive or use any machines or tools until you know how Diazepam Elixir® affects you.**

Diazepam Elixir® may cause drowsiness or dizziness in some people and therefore may affect alertness.

### Drinking alcohol

**Tell your doctor if you drink alcohol.**

Be careful when drinking alcohol while taking Diazepam Elixir®. Combining Diazepam Elixir® and alcohol can make you more sleepy, dizzy or lightheaded.

Your doctor may suggest that you avoid alcohol or reduce the amount of alcohol you drink while you are taking Diazepam Elixir®.

### Looking after your medicine

- **Store below 25°C**

Store it in a cool dry place away from moisture, heat or sunlight; for example, do not store it:

- in the bathroom or near a sink, or
- in the car or on window sills.

Follow the instructions on the label on how to take care of your medicine properly.

Keep your Diazepam Elixir® in its bottle until it is time to take it. If you take the elixir out of the bottle it may not keep well.

**Keep it where children cannot reach it.**

A locked cupboard at least one-and-a-half metres above the ground is a good place to store medicines.

Do not use Diazepam Elixir® if the bottle or cap is broken or shows signs of tampering.

### When to discard your medicine

**After opening discard after 90 days.**

## Getting rid of any unwanted medicine

If you no longer need to use this medicine or it is out of date, take it to any pharmacy for safe disposal.

Do not use this medicine after the expiry date. It may have no effect at all, or worse, an entirely unexpected effect if you use it after the expiry date.

## 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.

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

### Less serious side effects

Less serious side effects	What to do
<b>Nervous system disorders:</b> <ul style="list-style-type: none"><li>• tiredness, drowsiness</li><li>• dizziness, unsteadiness</li><li>• loss of memory, inattentiveness, confusion, lack of concentration</li><li>• headache, hangover feeling in the morning</li><li>• slurred speech</li><li>• unpleasant dreams</li></ul>	<b>Speak to your doctor if you have any of these less serious side effects and they worry you.</b>

### Serious side effects

Serious side effects	What to do
<b>Nervous system disorders:</b> <ul style="list-style-type: none"><li>• sudden anxiety or excitation</li><li>• restlessness, agitation, irritability, anger</li><li>• hallucinations or delusions</li><li>• severe sleep disturbances</li></ul> <b>Respiratory disorders or breathing-related:</b> <ul style="list-style-type: none"><li>• difficulties in breathing or choking or coughing</li></ul> <b>Hepatobiliary disorders:</b> <ul style="list-style-type: none"><li>• yellowing of the skin and/or eyes (jaundice)</li></ul>	<b>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.</b>

**Tell your doctor or pharmacist if you notice anything else that may be making you feel unwell when you are taking, or soon after you have finished taking, Diazepam Elixir®.**

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](http://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 taking any of your medicines.**

## 7. Product details

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

### What Diazepam Elixir® contains

<b>Active ingredient (main ingredient)</b>	Diazepam
<b>Other ingredients (inactive ingredients)</b>	Ethanol Propylene glycol Glycerol Citric acid Sodium citrate dihydrate Purified water Blackcurrant flavour

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

Diazepam Elixir® does not contain gluten, lactose, sucrose, tartrazine or any other azo dyes.

### What Diazepam Elixir® looks like

Diazepam Elixir® is a clear, colourless to yellow, slightly viscous liquid with an odour of blackcurrant available in a 100mL amber glass bottle

Australian Registration Number AUST R 42852

### Who distributes Diazepam Elixir®

Orion Laboratories Pty Ltd T/A Evaris Pharma  
25 – 29 Delawney Street  
Balcatta WA 6021  
[www.evarispharma.com](http://www.evarispharma.com)

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