DIAZEPAM ELIXIR ®

Diazepam Elixir 10mg/10mL

Consumer Medicine Information

Date of dispensing _____

Consumer Name _____ ***Pharmacist Name*** _____

Consumer Address _____ ***Pharmacist Address*** _____

What is in this leaflet?

This leaflet answers some common questions about Diazepam Elixir. It does not contain all the available information.

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

All medicines have benefits and risks. Your doctor has weighed the risks of you taking Diazepam Elixir against the benefits this medicine is expected to have for you.

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

Keep this leaflet with the medicine.
You may need to read it again.

What Diazepam Elixir is used for:

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

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with alcohol withdrawal. It is also used to treat panic attacks.

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

Diazepam Elixir 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 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.

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

Before you take Diazepam Elixir:

When you must not take Diazepam Elixir:

Do not take Diazepam Elixir if:

1. 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.

2. You have severe and chronic lung disease.

3. You suffer from severe muscle weakness known as myasthenia gravis.

4. You suffer from severe liver disease.

5. You have temporary stops in breathing during sleep.

6. You have drug or alcohol addiction.

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

Do not use Diazepam Elixir after the expiry date printed on the bottle.
It may have no effect at all, or worse, an entirely unexpected effect if you use it after the expiry date.

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.

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Before you start to take Diazepam Elixir:

You must tell your doctor if:

1. You have allergies to:

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

2. Do not use Diazepam Elixir if you are pregnant or plan to become pregnant.
It is not known whether Diazepam Elixir is harmful to an unborn baby when taken by a pregnant woman. If there is a need to take Diazepam Elixir when you are pregnant your doctor will discuss the risks and benefits to you and the unborn baby.

3. Do not use Diazepam Elixir if you are breast-feeding or plan to breast feed, unless you and your doctor have discussed the risks and benefits involved.
Diazepam may pass into the breast milk and cause drowsiness and/or feeding difficulties in the infant. Diazepam Elixir is not recommended for use while breast feeding.

4. 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.

5. You drink alcohol regularly.
Alcohol may increase the effects of Diazepam Elixir,

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alcohol should therefore be avoided during treatment.

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

Taking other medicines:

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

Some medicines may interfere with Diazepam Elixir. 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.

If you have not told your doctor about any of the above, tell

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them before you start taking Diazepam Elixir.

How to take Diazepam Elixir:

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

Your doctor or pharmacist will tell you how much elixir you will need to take each day. This depends on your condition and whether or not you are taking any other medicines.

If you do not understand the instructions on the box/bottle, ask your doctor or pharmacist for help.

How much to take:

Take Diazepam Elixir exactly as your doctor has prescribed.
Your doctor will decide the right dose for you. 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

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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.

Continue taking Diazepam Elixir as long as your doctor recommends it.

If you forget to take it:

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 use your medicine, ask your pharmacist for some hints.

If you take too much Diazepam Elixir (overdose):

Immediately telephone your doctor or the Poisons Information Centre (telephone 13 11 26), or go to casualty at your nearest hospital, if you think that you or anyone else may have

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used too much Diazepam Elixir. Do this even if there are no signs of poisoning. Also report any other medicine or alcohol which has been taken. You may need urgent medical attention. Keep telephone numbers for these places handy.

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

If you are not sure what to do, contact your doctor or pharmacist.

While you are using Diazepam Elixir:

Things you must do:

Use Diazepam Elixir exactly as your doctor has prescribed.

Tell all doctors, dentists, and pharmacists who are treating you that you are taking 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 you 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 must not do:

Do not drive or operate machinery until you know how Diazepam Elixir affects you.
Diazepam Elixir may cause drowsiness or dizziness in some people and therefore may affect alertness.

Make sure you know how you react to Diazepam Elixir before you drive a car, operate machinery, or do anything else that could be dangerous if you are drowsy, dizzy or not alert.

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 other wise by your doctor.

Do not change your dose without first checking with 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 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.

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.

Side effects:

Check with your doctor as soon as possible if you have any problems while taking Diazepam Elixir, even if you do not think the problems are connected with this medicine

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or are not listed in this leaflet.
Like other medicines, Diazepam Elixir can cause some side effects. If they occur, most are likely to be minor and temporary. However, some may be serious and need medical attention.

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

Tell your doctor if you notice any of the following and they worry you.

- tiredness, drowsiness,
- dizziness, unsteadiness
- loss of memory, inattentiveness, confusion, lack of concentration
- headache, hangover feeling in the morning
- slurred speech
- unpleasant dreams

These side effects listed above are the more common side effects of Diazepam Elixir.
Tell your doctor immediately or go to casualty at your nearest hospital if you notice any of the following:

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

These are serious side effects. You may need urgent medical attention. Serious side effects such as those above are rare.

Other side effects not listed above may occur in some patients. Tell your doctor if you notice anything else that is making you feel unwell when you are taking, or soon after you have finished taking Diazepam Elixir.

After using Diazepam Elixir:

Storage

Keep your 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 Diazepam Elixir in a cool dry place where the temperature stays below 25°C. Do not store it or any other medicines, in the bathroom or near a sink. Do not leave it in the car or on window sills.
Heat and dampness can destroy some medicines.

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.

Disposal

If your doctor tells you to stop taking Diazepam Elixir or the elixir has passed its expiry date, ask your pharmacist what to do with any that is left over.

Product Description:

What it looks like
Diazepam Elixir: 10mg/10mL, a clear, colourless to yellow, slightly viscous liquid with an odour of blackcurrant in 100mL bottle.

Ingredients
Active ingredient: 10mg/10mL of Diazepam
Inactive ingredients: ethanol, propylene glycol, glycerol, citric acid anhydrous, sodium citrate, purified water and blackcurrant flavour. Diazepam Elixir does not contain gluten, lactose, sucrose, tartrazine or any other azo dyes.

Manufacturer/Distributor:

Orion Laboratories Pty Ltd
25 – 29 Delawney Street
Balcatta WA 6021

Australian Registration Number: AUST R 42852

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