

GenRx® Diazepam

Diazepam (dye-AZ-e-pam)

Consumer Medicine Information

For a copy of a large print leaflet Ph: 1800 195 055

What is in this leaflet

This leaflet answers some common questions about GenRx Diazepam. 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 taking diazepam against the benefits they expect it will have for you.

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

Keep this leaflet with your medicine.

You may need to read it again.

What GenRx Diazepam is used for

Diazepam has sedative and muscle relaxant effects and is used to:

- treat anxiety (anxiety or tension associated with the normal stress of everyday life usually does not require treatment with medicines)
- relax muscles
- treat symptoms such as trembling, confusion and anxiety associated with alcohol withdrawal

This medicine belongs to a group of medicines called benzodiazepines.

These medicines are thought to work by their action on brain chemicals.

Ask your doctor if you have any questions about why this medicine has been prescribed for you.

Your doctor may have prescribed it for another reason.

In general, benzodiazepines such as diazepam should be taken for short periods only (for example 2 to 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.

Diazepam is not recommended for use in children under six months, as its safety and effectiveness have not been proven in this group.

Before you take GenRx Diazepam

When you must not take it

Do not take GenRx Diazepam if you have an allergy to:

- any medicine containing diazepam
- any of the ingredients listed at the end of this leaflet
- any other benzodiazepines.

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.

Do not take this medicine if you:

- suffer from severe muscle weakness known as myasthenia gravis
- have severe and chronic lung disease

- have temporary stops in breathing during sleep (sleep apnoea)
- have severe liver disease
- have drug or alcohol addiction (unless your doctor has prescribed it to help with relieving symptoms of alcohol withdrawal).

Do not take this medicine if the expiry date printed on the pack has passed or if the packaging is torn or shows signs of tampering.

If it has expired or is damaged return it to your pharmacist for disposal.

If you are not sure whether you should start taking this medicine, talk to your doctor.

Before you start to take it

Tell your doctor if you have allergies to any other medicines, foods, preservatives or dyes.

Tell your doctor if you have or have had any of the following medical conditions:

- depression
- psychosis or schizophrenia (mental conditions)
- memory loss
- epilepsy (fits or convulsions)
- liver, kidney or lung disease
- glaucoma (high pressure in the eye)
- low blood pressure.

Tell your doctor if you are pregnant or plan to become pregnant.

Like most benzodiazepines, diazepam is not generally recommended for use during pregnancy. Your doctor will discuss the risks and benefits of taking this medicine while pregnant.

Tell your doctor if you are breastfeeding or planning to breast-feed.

This medicine passes into breast milk and may cause drowsiness and/or feeding difficulties in your baby. Diazepam is not recommended for use while breast-feeding.

Tell your doctor if you drink alcohol regularly.

Alcohol may increase the effects of diazepam. Your doctor may advise you to avoid drinking alcohol while taking diazepam.

If you have not told your doctor about any of the above, tell him/her before you start taking this medicine.

Taking other medicines

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

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

- sedatives (medicines used to produce calmness or to help you sleep)
- medicines to control fits
- antipsychotics (medicines used to treat mental illness)
- medicines used to treat depression
- muscle relaxants
- antihistamines (medicines used to prevent or relieve the symptoms of allergy such as hay fever)
- anaesthetics

- cimetidine, omeprazole or cisapride (medicines used to treat gastric reflux and ulcers)
- disulfiram (a medicine used in the treatment of alcoholism)
- antibiotics such as erythromycin and ketoconazole
- atropine and similar medicines
- narcotic analgesics (strong pain relievers).

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

Your doctor and pharmacist have more information on medicines to be careful with or avoid while taking this medicine.

How to take GenRx Diazepam

Follow all directions given to you by your doctor or pharmacist carefully.

They may differ from the information contained in this leaflet.

If you do not understand the directions on the pack, ask your doctor or pharmacist for help.

How much to take

The dose of diazepam that your doctor prescribes for you will depend on your condition.

How to take it

Swallow diazepam tablets with a full glass of water.

When to take it

Your doctor will tell you how many times a day you should take your diazepam tablets.

Diazepam tablets can be taken with or without food.

How long to take it

Take diazepam tablets only for as long as your doctor recommends and no longer.

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 your medicine as you would normally.

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

This may increase the chance of you getting an unwanted side effect.

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

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

If you take too much (overdose)

Immediately telephone your doctor or the Poisons Information Centre (telephone 13 11 26) for advice, or go to Accident and Emergency at your nearest hospital, if you think that you or anyone else may have taken too much diazepam.

Do this even if there are no signs of discomfort or poisoning. Also report any other medicine or alcohol which has been taken.

You may need urgent medical attention.

Symptoms of an overdose may include severe drowsiness or tiredness, dizziness, confusion, irritability, weakness, having difficulty breathing or unconsciousness. It is important that you recognise these signs of overdose early.

While you are taking GenRx Diazepam

Things you must do

If you are about to be started on any new medicines, remind your doctor or pharmacist that you are taking diazepam.

Tell all doctors, dentists and pharmacists who are treating you that you are taking this medicine.

If you are going to have surgery, tell the surgeon or anaesthetist that you are taking this medicine.

It may affect other medicines used during surgery.

If you become pregnant while you are taking this medicine, tell your doctor immediately.

It is best to avoid drinking alcohol while taking this medicine.

Combining diazepam 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.

Keep all of your doctor's appointments so that your progress can be checked.

Your doctor needs to check your progress and see whether you need to keep taking this medicine.

Always discuss with your doctor any problems or difficulties during or after taking this medicine.

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.

Things you must not do

Do not take diazepam to treat any other complaints unless your doctor tells you to.

Do not give your medicine to anyone else, even if they have the same condition as you.

Do not drive or operate machinery until you know how diazepam affects you.

This medicine may cause drowsiness or dizziness in some people and therefore may affect alertness. Even if you take this medicine at night, you may still be drowsy or dizzy the next day.

If you are drowsy or dizzy, do not drive.

Do not take diazepam for a longer time than your doctor has prescribed.

Diazepam should be taken for short periods only (for example 2 to 4 weeks), unless advised otherwise by your doctor.

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

Stopping this medicine suddenly may cause some unwanted effects. Your doctor may decide to slowly reduce your dose of diazepam before you can stop taking it completely.

Do not suddenly stop taking diazepam if you suffer from epilepsy.

Stopping this medicine suddenly may make your epilepsy worse.

Do not let yourself run out of medicine on weekends or holidays.

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.

Side effects

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are taking diazepam.

This medicine helps most people with anxiety or muscle spasm but it may have unwanted side effects in some people. All medicines may 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 elderly, unwell or taking other medicines, you may have an increased chance of getting side effects.

Do not be alarmed by the following lists of side effects. You may not experience any of them.

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

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

- drowsiness, tiredness
- dizziness, lightheadedness
- clumsiness or unsteadiness
- slurred speech
- headache
- constipation

The above list includes the more common side effects of your medicine. They are usually mild and may disappear if the dose is reduced.

Tell your doctor as soon as possible if you notice any of the following:

- blurred vision
- mood changes
- sudden anxiety or excitation
- severe sleep disturbances
- tremor
- memory problems (amnesia)
- coordination problems
- agitation
- concentration difficulties
- confusion
- hallucinations (seeing, feeling or hearing things that are not there)
- irritability
- changes in libido
- incontinence or difficulty urinating.

The above list includes serious side effects which may require medical attention. Serious side effects are rare.

If any of the following happen tell your doctor immediately or go to Accident and Emergency at your nearest hospital:

- yellowing of the skin and/or eyes (jaundice)
- skin rash
- sudden anxiety or excitation
- irritability or aggressiveness
- severe sleep disturbances
- hallucinations
- increased muscle spasticity (prolonged stiffness and restricted movement in a group of muscles).

The above list includes very serious side effects. You may need urgent medical attention or hospitalisation. These side effects are rare.

Tell your doctor or pharmacist if you notice anything that is making you feel unwell.

Other side effects not listed above may also occur in some people.

After using GenRx Diazepam

Storage

Keep your tablets in their packaging until it is time to take them.

If you take the tablets out of the packaging they may not keep well.

Keep your tablets in a cool dry place protected from light where the temperature stays below 25°C.

Do not store diazepam, or any other medicines in a bathroom or near a sink. Do not leave it on a window sill or in the car.

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 this medicine or the expiry date has passed, ask your pharmacist what to do with any medicine that is left over.

Product description

What it looks like

GenRx Diazepam 2mg: white to off-white round, curved tablets with a '2' on one side and plain on the other side. They are available in blister packs of 50 tablets.

Aust R: 93666

GenRx Diazepam 5mg: white to off-white round, flat tablets with a '5' and a scoreline on one side and plain on the other side. They are available in blister packs of 50 tablets.

Aust R: 93667

Ingredients

GenRx Diazepam tablets contain 2mg or 5mg diazepam as the active ingredient. They also contain:

- lactose
- starch - maize
- silica-colloidal anhydrous
- magnesium stearate
- purified talc.

This medicine does not contain gluten, sucrose, tartrazine or any other azo dyes.

Sponsor

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Australia

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