

APO- Diazepam Tablets

Contains the active ingredient 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

Read this leaflet carefully before taking your medicine.

This leaflet answers some common questions about APO- Diazepam. It does not contain all the available information. It does not take the place of talking to your doctor or pharmacist.

The information in this leaflet was last updated on the date listed on the last page. More recent information on this medicine may be available.

Ask your doctor or pharmacist:

- if there is anything you do not understand in this leaflet,
- if you are worried about taking your medicine, or
- to obtain the most up-to-date information.

You can also download the most up to date leaflet from www.apotex.com.au.

All medicines have risks and benefits. Your doctor has weighed the risks of you using this medicine against the benefits they expect it will have for you.

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

Pharmaceutical companies cannot give you medical advice or an individual diagnosis.

Keep this leaflet with your medicine. You may want to read it again.

What this medicine is used for

The name of your medicine is APO-Diazepam. It contains the active ingredient diazepam.

This medicine is used to:

- treat anxiety disorders. Anxiety or tension associated with the normal stress of everyday life usually does not require treatment with medicines.
- stop muscle spasms and relax muscles
- treat trembling, confusional states or anxiety associated with alcohol withdrawal.
- panic attacks.

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

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

How it works

This medicine belongs to a group of medicines called benzodiazepines.

It is thought to work by acting on chemicals in the brain.

Benzodiazepines are not recommended as the only treatment of severe mental illnesses and should not be used alone to treat depression or severe mental illness.

Ask your doctor if you have any questions about why APO-Diazepam has been prescribed for you.

In general, benzodiazepines such as diazepam should be taken for short periods only (around 2 to 4 weeks). Continuous long-term use is not recommended unless advised by your doctor.

There is evidence that using these types of medicines can lead to dependence.

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

Use in children

Children younger than 6 months old should not be given this medicine.

Before you take this medicine

When you must not take it

Do not take this medicine if:

- you have severe and chronic lung disease
- you have severe liver disease
- you suffer from sleep apnoea (temporary stops in breathing during sleep)
- you suffer from myasthenia gravis (a disease which causes severe muscle weakness)
- you are addicted to drugs or alcohol (unless your doctor has prescribed diazepam to help to relieve the symptoms of alcohol withdrawal)
- the expiry date (EXP) printed on the pack has passed. If you take this medicine after the expiry date has passed, it may not work as well.
- the packaging is torn or shows signs of tampering or it does not look quite right.
- You are hypersensitive to, or have had an allergic reaction to, diazepam, any other benzodiazepine medicine, or any ingredients listed at the end of this leaflet.

Symptoms of an allergic reaction may include: cough, shortness of breath, wheezing or difficulty breathing; swelling of the face, lips, tongue, throat or other parts of the body; rash, itching or hives on the skin; fainting; or hay fever-like symptoms

If you think you are having an allergic reaction, do not take any more of the medicine and contact your doctor immediately or go to the Accident and Emergency department at the nearest hospital.

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

Before you start to take it

Before you start taking this medicine, you must tell your doctor if:

1. You have allergies to:
 - any other medicines
 - any other substances, such as foods, preservatives or dyes.
 - lactose, these tablets contain lactose
2. You have or have had any medical conditions, especially the following:
 - liver, kidney or lung problems
 - high or low blood pressure
 - narrow or acute angle glaucoma (raised pressure in the eye)
 - memory loss
 - depression, psychosis, schizophrenia or other mental illness
 - epilepsy (fits or convulsions)
 - history of alcohol or drug abuse
3. You drink alcohol. Alcohol may increase the effects of diazepam and for example may result in excessive drowsiness.
The same effect may also be seen with other medicines which make you sleepy.
4. You are currently pregnant or you plan to become pregnant. It is not known whether this medicine is harmful to an unborn baby

when taken by a pregnant woman. If there is a need to take this medicine when you are pregnant your doctor will discuss the risks and benefits to you and the unborn baby.

5. You are currently breastfeeding or you plan to breast-feed. Do not take this medicine whilst breastfeeding until you and your doctor have discussed the risks and benefits involved. APO-Diazepam may pass into the breast milk and cause drowsiness and/or feeding difficulties in the baby. APO-Diazepam is not recommended for use while breastfeeding.
6. You are planning to have surgery or an anaesthetic.
7. You are currently receiving or are planning to receive dental treatment.

Taking other medicines

Tell your doctor if you are taking or are planning to take any other medicines. This includes vitamins and supplements that are available from your pharmacy, supermarket or health food shop.

Some medicines can interfere with your treatment. Tell your doctor if you are taking or planning to take any of the following:

- other sleeping tablets, sedatives or tranquilisers
- medicines used to treat mental disorders, including depression
- medicines used to treat epilepsy (fits or convulsions)
- medicines for allergies or colds (e.g. antihistamines)
- atropine and similar medicines, used for stomach problems, in operations and also sometimes after heart attacks
- strong pain relievers
- muscle relaxants
- anaesthetics (used during operations)
- cimetidine, omeprazole- a medicine used to treat ulcers
- cisapride-a medicine used to treat gastric reflux disulfiram,
- disulfiram - a medicine used in alcohol abuse
- a medicine used to help treat alcoholism
- ketoconazole, a medicine used to treat fungal infections
- medicines used to treat thyroid problems
- diltiazem, a medicine used to treat high blood pressure and heart conditions.

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.

Other interactions not listed above may also occur.

If you are taking any other medications, check with your doctor before you start to take diazepam.

How to take this medicine

Follow carefully all directions given to you by your doctor.

They may differ from the information contained in this leaflet.

How much to take

Take diazepam only as directed by your doctor.

Your doctor will tell you how much of this medicine you should take. The dose varies from person to person depending on age and the condition being treated and whether you are taking any other medicines.

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

Do not stop taking your medicine suddenly, or change the dosage, without checking with your doctor.

When it is time to stop taking diazepam your doctor will tell you how to do this gradually.

How to take it

Swallow the tablets whole, with a full glass of water.

When to take it

Take your medicine at about the same time each day.

Taking it at the same time each day will have the best effect. It will also help you remember when to take it.

It does not matter if you take it before, with or after food.

How long to take it for

Continue taking your medicine for as long as your doctor tells you.

Usually, diazepam should be taken for short periods only (for example, for 2 to 4 weeks). Continuous long-term use is not recommended unless advised by your doctor. Dependence may develop from using benzodiazepines such as diazepam.

If you forget a dose

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 experiencing side effects.

If you are not sure whether to skip the dose, talk to 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.

You may need urgent medical attention.

Keep telephone numbers for these places handy.

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

If you take too much diazepam, you may feel drowsy, tired, confused, dizzy, have difficulty breathing, feel weak or become unconscious. It is important that you recognise these signs of overdose early.

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

While you are taking this medicine

Things you must do

Tell any other doctors, dentists and pharmacists who are treating you that you take this medicine.

Tell your doctor that you are taking this medicine if:

- you are about to be started on any new medicine, whether they require a prescription or not
- you are pregnant or are planning to become pregnant
- you are breastfeeding or are planning to breast-feed
- you are about to have any blood tests
- you are going to have surgery or an anaesthetic or are going into hospital.

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.

Tell your doctor if you feel the tablets are not helping your condition.

Be sure to keep all of your appointments with your doctor so that your progress can be checked.

Things you must not do

Do not:

- Drive or operate machinery until you know how diazepam affects you. This medicine may cause dizziness and tiredness in some people and therefore may affect alertness. If you have any of these symptoms, do not drive, or operate machinery or do anything else that is dangerous
- Give this medicine to anyone else, even if their symptoms seem similar to yours.
- Take your medicine to treat any other condition unless your doctor tells you to.
- Stop taking your medicine, or change the dosage, without first checking with your doctor

Stopping this medicine suddenly may cause some side effects.

Your doctor may decide to slowly reduce your dose of diazepam before you can stop taking it completely.

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

Do not take this medicine for a longer time than your doctor has prescribed. APO-Diazepam should be taken for short periods only (for example 2 to 4 weeks) unless advised by your doctor.

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

Things to be careful of

Be careful:

- When drinking alcohol while taking diazepam. Combining diazepam and alcohol can make you more sleepy, dizzy or light-headed. Your doctor may suggest that you avoid alcohol or reduce the amount of alcohol you drink while you are taking this medicine.
- If you are elderly, unwell or taking other medicines. Some people may experience side effects such as drowsiness, confusion, dizziness, unsteadiness and/or a drop in blood pressure which may increase the risk of a fall.

- Avoid drinking grapefruit juice as it may affect the absorption of APO-Diazepam.

Possible side effects

Tell your doctor as soon as possible if you do not feel well while you are taking APO-Diazepam. APO-Diazepam helps most people with anxiety but it may have unwanted side effects in a few.

Do not be alarmed by the following lists of side effects. You may not experience any of them. All medicines can have side effects. Sometimes they are serious but most of the time they are not.

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

Tell your doctor if you notice any of the following:

- drowsiness, tiredness
- muscle weakness
- clumsiness or unsteadiness
- feeling sick, dizzy, giddy or light-headed
- loss of memory, inattentiveness, confusion, lack of concentration
- feeling depressed
- headache, hangover feeling in the morning
- problems speaking such as slurred speech
- blurred or double vision
- unpleasant dreams
- incontinence
- mild skin rash
- dry mouth or excessive saliva
- constipation, urinating less than normal
- increased or decreased libido (sex drive).

Tell your doctor immediately or go to the Accident and Emergency department at your nearest hospital if you notice any of the following:

These are very serious side effects and you may need urgent medical attention or hospitalisation.

- sudden anxiety or excitation
- restlessness, agitation, irritability, anger, abnormal behaviour
- hallucinations (seeing, feeling or hearing things that are not there) or delusions
- severe sleep disturbances
- difficulties in breathing or choking or coughing
- yellowing of the skin or eyes, and/or pale stools, dark urine (jaundice).

This is not a complete list of all possible side effects. Others may occur in some people and there may be some side effects not yet known.

Tell your doctor if you notice anything else that is making you feel unwell, even if it is not on this list.

Ask your doctor or pharmacist if you don't understand anything in this list.

Allergic reactions

If you think you are having an allergic reaction to APO-Diazepam, do not take any more of this medicine and tell your doctor immediately or go to the Accident and Emergency department at your nearest hospital.

Symptoms of an allergic reaction may include some or all of the following:

- cough, shortness of breath, wheezing or difficulty breathing
- swelling of the face, lips, tongue, throat or other parts of the body
- rash, itching or hives on the skin
- fainting

- hay fever-like symptoms.

Storage and disposal

Storage

Keep your medicine in its original packaging until it is time to take it.

If you take your medicine out of its original packaging it may not keep well.

Keep your medicine in a cool dry place where the temperature will stay below 25°C.

Do not store your medicine, or any other medicine, in the 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 this medicine 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 APO- Diazepam 2mg tablets looks like

White to off-white, round biconvex, uncoated tablets debossed with "2" on one side and plain on the other.

What APO- Diazepam 5mg tablets looks like

White to off-white, round flat bevelled-edge, uncoated tablets debossed with "5" and a scoreline on one side and plain on the other.

Available in blister packs of 50 tablets.

* Not all strengths may be available.

Ingredients

Each tablet contains 2 mg or 5 mg of diazepam, as the active ingredient.

They also contain the following inactive ingredients:

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

These tablets do not contain gluten, sucrose, tartrazine or any other azo dyes.

Contains sugars as lactose.

Australian Registration Numbers

APO-Diazepam 2 mg tablets:

AUST R 134472

APO-Diazepam 5 mg tablets:

AUST R 134590

Sponsor

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