

APO-Diazepam Tablets

Contains the active ingredient, Diazepam (dye-AZ-e-pam)

Consumer Medicine Information

What you need to know about APO-Diazepam Tablets

Your doctor has weighed the risks and expected benefits of diazepam and decided to prescribe this medicine to help treat your condition.

Read this leaflet carefully before you start to take this medicine. It contains important information.

Keep the leaflet in a safe place because you may want to read it again.

If you have any other questions, or if there is something you don't understand please ask your doctor or pharmacist for advice.

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

This medicine has been prescribed for you. You should never give it to anyone else. It may not be the right medicine for them even if their symptoms seem to be the same as yours.

If you develop any side effects that are serious or if you notice any side effects that are not listed in this leaflet, tell your doctor or pharmacist immediately or go to the nearest hospital. Also look at Section 4: "Possible side effects".

What is in this leaflet

1. What APO-Diazepam tablets are for
2. Things to consider before you take APO-Diazepam tablets
3. How to take this medicine
4. Possible side effects
5. How to store this medicine

6. Further information

The information in this leaflet was last updated on the date listed on the last page. Some more recent information on your medicine may be available. Speak to your pharmacist or doctor to obtain the most up-to-date information.

1. What APO-Diazepam tablets are for

This medicine is used for a short period of time only to:

- treat anxiety disorders (including panic attacks).
- stop muscle spasms and relax muscles
- treat symptoms associated with alcohol withdrawal, such as trembling and agitation.

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.

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.

Benzodiazepines should not be used alone to treat depression or severe mental illness.

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.

Diazepam is only available with a doctor's prescription.

Use in children

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

2. Things to consider before you take APO-Diazepam tablets

When you must not take it

People who are allergic to diazepam, any of the inactive ingredients or other benzodiazepines MUST NOT take these tablets.

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
- skin rash, itching or hives

Talk to your doctor if you think you may be allergic to diazepam, benzodiazepines or to any of the other ingredients in these tablets.

Do not take this medicine if:

- you have severe 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.

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

Do not give this medicine to children less than six months old.

Ask yourself the following questions before taking diazepam tablets.

If the answer to any of these questions is YES, tell your doctor or pharmacist.

- **Do you have allergies to any other medicines, foods, preservatives or dyes?**
- **Are you intolerant of or allergic to lactose?**

These tablets contain lactose.

- **Do you have, or have you had any of the following medical conditions:**
 - liver, kidney or lung problems
 - high or low blood pressure
 - narrow or acute angle glaucoma (raised pressure in the eye)
 - memory loss
 - depression or severe mental illness such as psychosis or schizophrenia
 - epilepsy (fits or convulsions).
- **Are you pregnant or planning to become pregnant?**

It is not known for certain whether this medicine is harmful to an unborn baby when taken by a pregnant woman, but newborn

babies may be affected, and also have withdrawal symptoms. If there is a need to take diazepam when you are pregnant, your doctor will discuss the risks and benefits to you and the unborn baby.

- **Are you breast-feeding or planning to breast-feed?**

Diazepam may pass into the breast milk and cause drowsiness and/or feeding difficulties in the baby. Diazepam is not recommended for use while breast-feeding. Your doctor can explain the risks and benefits to you and the newborn baby.

- **Do you drink alcohol?**

Alcohol combined with diazepam may increase the effects of each other, for example, excessive drowsiness.

The same effect can also be seen with other medicines which can make you sleepy.

- **Are you taking other medicines?**

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

- Any medicines that you get without a prescription from your pharmacy, supermarket or health food shop
- other sleeping tablets, sedatives or tranquillisers
- medicines used to treat depression
- medicines used to treat epilepsy
- medicines used to treat severe mental problems
- 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 or cisapride, medicines used to treat ulcers or reflux
- disulfiram, a medicine used to help treat alcoholism
- ketoconazole, a medicine used to treat fungal infections
- medicines used to treat thyroid problems.

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.

3. How to take this medicine

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 any written instructions, ask your doctor or pharmacist for help.

How much to take

Take diazepam only as directed by your doctor.

Your doctor has carefully chosen your dose of diazepam according to your medical condition, age, body weight and any other medical conditions that you may have.

The usual adult dose is usually between 5 and 40 mg daily. Elderly and very ill patients will need to take much less. Children's doses may depend on their age and weight.

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 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

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 getting an unwanted side effect.

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.

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

Things you must do

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

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

Tell your doctor immediately if you become pregnant.

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.

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.

Your doctor may perform tests to make sure the medicine is working and to watch for unwanted side effects.

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

Combining diazepam with 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 diazepam.

Things you must not do

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

Diazepam may cause drowsiness or dizziness in some people and therefore may affect alertness. Make sure you know how you react to this medicine before you drive a car or operate machinery or do anything else that could be dangerous if you are drowsy, dizzy or not alert. Even if you take this medicine at night, you may still be drowsy or dizzy the next day.

Do not take this medicine 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 by your doctor.

Do not stop taking diazepam suddenly or change the dose, without first checking with your doctor.

Stopping this medicine suddenly may cause some unwanted effects such as disturbed sleep. Also, if you suffer from epilepsy, stopping this medicine suddenly may make your epilepsy worse.

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

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

Things to be careful of

Be careful driving or operating machinery until you know how diazepam affects you.

This medicine may cause dizziness and tiredness in some people. If you have any of these symptoms, do not drive, or operate machinery or do anything else that is dangerous.

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.

Be careful 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.

Some people may also become depressed or have problems breathing.

Sometimes people may also have problems remembering things.

4. Possible side effects

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

All medicines can have side effects. Sometimes they are serious, most of the time, they are not. You may need medical treatment if the side effects are serious.

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 get any of them.

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

If any of the following happen, do not use any more of your medicine and either tell your doctor IMMEDIATELY or go to Accident and Emergency at your nearest hospital:

- You have an allergic reaction to the medicine, with symptoms such as cough, shortness of

breath, wheezing or difficulty breathing, swelling of the face, lips, tongue, or other parts of the body, hay fever, rash, itching or hives on the skin, fainting

- you think you are having a heart attack, with typical symptoms such as chest pain or tightness, squeezing, pressure, or fullness in the chest which may radiate to the shoulders, back, neck, jaw or arms. This may be accompanied by extreme sweating, shortness of breath, fatigue, chills, nausea and vomiting, anxiety, paleness, or bluish coloured lips, feet and hands. Unconsciousness may follow.

These side effects are usually rare but may be serious and require urgent medical attention.

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

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

These may be serious side effects. You may need medical attention. Most of these side effects are rare.

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

- drowsiness, tiredness
- muscle weakness
- clumsiness or unsteadiness
- feeling sick, dizzy, giddy or light-headed
- loss of memory, inappropriate behaviour, inattentiveness, confusion, lack of concentration
- feeling depressed
- headache, hangover feeling in the morning

- problems speaking such as slurred speech
- trembling
- blurred or double vision
- incontinence
- unpleasant dreams
- mild skin rash
- dry mouth or excessive saliva
- constipation, urinating less than normal
- increased or decreased libido (sex drive).

The above list includes side effects which are usually mild. They may be short-lived.

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

Ask your doctor or pharmacist if you do not understand anything in this list.

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.

Some side effects can only be found when your doctor does tests from time to time to check your progress.

5. How to store this medicine

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

If you take the tablets out of the blister pack, they may not keep as well.

Keep them in a cool dry place, protected from light and where the temperature stays below 25°C.

Do not store your medicine, or any other medicines 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 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.

6. Further Information

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

What it looks like

APO-Diazepam 2 mg tablets

White to off-white round, curved tablets with a '2' on one side and plain on the other side.

APO-Diazepam 5 mg tablets

White to off-white round, flat tablets with a '5' and a scoreline on one side and plain on the other side.

Available in blister packs of 50 tablets.

Ingredients

APO-Diazepam tablets

contain 2 mg or 5 mg of diazepam, as the active ingredient.

They also contain the following inactive ingredients:

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

Australian Registration Numbers

APO-Diazepam 2 mg tablets

AUST R 134472

APO-Diazepam 5 mg tablets

AUST R 134590

Sponsor

Apotex Pty Ltd

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Australia

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