

APX-DIAZEPAM

diazepam

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about APX-DIAZEPAM. It does not contain all of 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 APX-DIAZEPAM against the benefits they expect it will have for you.

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

Keep this leaflet with your medicine.

You may need to read it again.

What APX-DIAZEPAM is used for

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

APX-DIAZEPAM is used to relax muscles.

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

APX-DIAZEPAM belongs to a group of medicines called benzodiazepines.

They are thought to work by their action on brain chemicals.

Benzodiazepines are not recommended as the only treatment

of severe mental illnesses and should not be used alone to treat depression.

Your doctor, however, may have prescribed APX-DIAZEPAM for another purpose.

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

In general, benzodiazepines such as APX-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.

The use of benzodiazepines may lead to dependence on the medicine.

APX-DIAZEPAM is available only with a doctor's prescription.

Before you take it

Do not take APX-DIAZEPAM if:

- 1. you have had an allergic reaction to APX-DIAZEPAM, any other benzodiazepine medicine or any ingredients listed at the end of this leaflet**
- 2. you have severe and chronic lung disease**
- 3. you have severe liver disease**
- 4. you have temporary stops in breathing during sleep**
- 5. you suffer from severe muscle weakness**
- 6. you have drug or alcohol addiction**
- 7. the packaging is torn or shows signs of tampering**

8. 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.

If you are not sure whether you should be taking APX-DIAZEPAM, talk to your doctor.

Do not give APX-DIAZEPAM to children less than six months old.

Before you start to take it

Your doctor must know about all the following before you start to take APX-DIAZEPAM.

1. if you are pregnant or plan to become pregnant

It is not known whether APX-DIAZEPAM is harmful to an unborn baby when taken by a pregnant woman. If there is a need to take APX-DIAZEPAM when you are pregnant your doctor will discuss the risks and benefits to you and the unborn baby.

2. if you are breastfeeding or plan to breastfeed

APX-DIAZEPAM may pass into the breast milk and cause drowsiness and/or feeding difficulties in the baby. APX-DIAZEPAM is not recommended for use while breastfeeding.

3. if you have any other health problems including:

- liver, kidney or lung disease
- high or low blood pressure
- glaucoma (high pressure in the eye)
- depression, schizophrenia or other mental illness
- epilepsy (fits)

- history of alcohol or drug abuse
- 4. if you drink alcohol**
Alcohol may increase the effects of APX-DIAZEPAM.
- 5. if you are allergic to any other medicines, foods, dyes or preservatives.**

Taking other medicines

Tell your doctor 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 may interfere with APX-DIAZEPAM. These medicines include:

- other sleeping tablets, sedatives or tranquillisers
- medicines used for depression
- medicines to control fits
- medicines for allergies or colds such as antihistamines
- pain relievers
- muscle relaxants
- cimetidine and omeprazole- a medicine used to treat ulcers
- disulfiram - a medicine used in alcohol abuse
- cisapride-a medicine used to treat gastric reflux
- ketoconazole- a medicine used to treat fungal infections

These medicines may be affected by APX-DIAZEPAM or may affect how well APX-DIAZEPAM works. Your doctor or pharmacist can tell you what to do if you are taking any of these medicines. They also have a more complete list of medicines to be careful with or avoid while taking APX-DIAZEPAM.

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

How to take it

How much to take

Take APX-DIAZEPAM exactly as your doctor has prescribed.

Your doctor will tell you how many APX-DIAZEPAM tablets to take each day.

The dose varies from person to person depending on age and the condition being treated. The usual adult dose is between 5 and 40 mg daily. Children, elderly and very ill patients may need to take less.

How to take it

Swallow the tablets with a glass of water.

When to take it

APX-DIAZEPAM can be taken up to three times a day. Your doctor will tell you how much you need to take. The tablets can be taken with or without food.

How long to take it for

APX-DIAZEPAM 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.

Continue taking APX-DIAZEPAM until your doctor tells you to stop.

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 the missed dose as soon as you remember, and then go back to taking your tablets as you would normally.

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

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

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 the nearest hospital if you think you or anyone else may have taken too much APX-DIAZEPAM. Do this even if there are no signs of discomfort or poisoning.

You may need urgent medical attention.

If you have taken too much APX-DIAZEPAM, you may feel drowsy, tired, confused, 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 taking it

Things you must do

Tell all doctors, dentists and pharmacists who are treating you that you are taking APX-DIAZEPAM.

Do not take any other medicines whether they require a prescription or not without first telling your doctor.

Tell your doctor if you become pregnant while taking APX-DIAZEPAM.

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 APX-DIAZEPAM affects you. APX-DIAZEPAM may cause drowsiness or dizziness in some people and therefore may affect alertness. Make sure you know how you react to APX-DIAZEPAM before you drive a car or operate machinery or do anything else that could be dangerous if you are drowsy, dizzy or not alert.

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

Do not stop taking APX-DIAZEPAM 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 of APX-DIAZEPAM before you can stop taking it completely.

Do not let yourself run out of medicine over the weekend or on holidays.

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

Do not give APX-DIAZEPAM to anyone else even if their symptoms seem similar to yours.

Do not use APX-DIAZEPAM to treat other complaints unless your doctor says so.

Things to be careful of

Be careful if you are elderly, unwell, drinking alcohol 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.

Your doctor may suggest that you avoid alcohol or reduce the amount

of alcohol you drink while you are taking APX-DIAZEPAM.

Avoid drinking grapefruit juice as it may affect the absorption of APX-DIAZEPAM.

Side effects

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

APX-DIAZEPAM helps most people with anxiety but it may have unwanted side effects in a few. All medicines can have side effects. Sometimes they are serious, most of the time they are not. Some side effects may require medical treatment.

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:

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

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

- sudden anxiety or excitation
- restlessness, agitation, irritability, anger, abnormal behaviour
- hallucinations or delusions
- severe sleep disturbances
- difficulties in breathing or choking or coughing wheezing or shortness of breath.

These are serious side effects. You may need urgent medical attention. Serious side effects are rare.

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.

Do not be alarmed by this list of possible side effects. You may not experience any of them.

After taking it

Storage

Keep your 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.

Keep your tablets in a cool dry place where the temperature stays below 30°C.

Do not store APX-DIAZEPAM or any other medicine 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.

Disposal

If your doctor tells you to stop taking APX-DIAZEPAM or your tablets have passed their expiry date, ask your pharmacist what to do with any that are left over.

Product description

What it looks like

APX-DIAZEPAM comes in 2 strengths of tablets:

APX-DIAZEPAM 2mg: round, flat, bevel edged, white to off-white tablet marked DZ/2 on one side and

plain on the other. Available in blister packs.

APX-DIAZEPAM 5mg: round, flat, bevel edged, light yellow tablet marked DZ/5 on one side and plain on the other. Available in bottle or blister packs.

Each pack contains 50 tablets.

Ingredients

The active ingredient in APX-DIAZEPAM is diazepam.

APX-DIAZEPAM 2mg: Each tablet contains 2 mg of diazepam.

APX-DIAZEPAM 5mg: Each tablet contains 5 mg of diazepam.

The tablets also contain:

- lactose monohydrate
- maize starch
- magnesium stearate.

APX-DIAZEPAM 5mg tablets also contain:

- quinoline yellow CI47005 (104).

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

Contains sugars as lactose.

Sponsor

Arrotex Pharmaceuticals Pty Ltd
15-17 Chapel Street
Cremorne VIC 3121

www.arrotex.com.au

Phone: 1800 195 055

Australian registration numbers:

APX-DIAZEPAM 2 mg blister pack: AUST R 335816

APX-DIAZEPAM 5 mg blister pack: AUST R 335814

APX-DIAZEPAM 5 mg bottle: AUST R 335813.

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