

NEW ZEALAND CONSUMER MEDICINE INFORMATION

Arrow - Diazepam

Diazepam 2mg and 5mg tablets

What is in this leaflet

This leaflet answers some common questions about ARROW - 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 ARROW - 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 ARROW - DIAZEPAM is used for

ARROW - DIAZEPAM contains diazepam. It belongs to a group of medicines called benzodiazepines. These medicines are thought to work by their actions on brain chemicals.

ARROW - DIAZEPAM is a sedative, muscle relaxant and anticonvulsant, used for the following conditions:

- severe anxiety, occurring alone or related to insomnia or mental illness
- tension headaches and migraine attacks where anxiety is the cause or aggravating factor
- symptoms of alcohol withdrawal, such as trembling, confusion or anxiety
- muscle spasm, including spasms of tetanus or cerebral spasticity (selected cases)
- some types of epilepsy
- premedication
- night terrors and sleep-walking, especially in children.

Like other benzodiazepines, ARROW - DIAZEPAM is not recommended as the sole treatment of severe mental illnesses and should not be used alone to treat depression.

Your doctor may have prescribed ARROW - DIAZEPAM for another reason. Ask your doctor if you have any questions about why ARROW - DIAZEPAM has been prescribed for you.

ARROW - DIAZEPAM is not recommended in children less than 6 months old.

In general, benzodiazepines 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 of the medicine.

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

Before you take ARROW - DIAZEPAM

When you must not take it

Do NOT take ARROW - DIAZEPAM if:

You are allergic to diazepam or any of the other ingredients listed at the end of this leaflet

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.

You have severe and chronic lung disease including asthma

You have myasthenia gravis

You or your child have attention deficit disorder (ADD)

You or your child have problems swallowing

You have an acute closed-angle glaucoma (increased pressure in the eye)

Do not use ARROW - DIAZEPAM if you are pregnant or planning on becoming pregnant or if you are breastfeeding.

Do not use ARROW - DIAZEPAM if the packaging is torn or shows signs of tampering.

Do not use ARROW - DIAZEPAM after the expiry (EXP) printed on the pack.

Before you take it

Tell your doctor if you are allergic to any other medicines, foods, dyes or preservatives.

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

- anxiety, depression or psychosis
- suicidal tendencies
- kidney or liver problems

- any lung or breathing problems
- drug or alcohol dependence

Your doctor may want to take special care if you have any of these conditions.

Taking other medicines

If you are taking any other medicines, including any you get without a prescription from a pharmacy, supermarket or health food shop, tell your doctor or pharmacist.

Some medicines may interfere with how well ARROW - DIAZEPAM works. These include:

- sleeping tablets, sedatives or tranquilisers
- medicines to treat depression or mental illness
- strong pain-relievers
- medicines to treat reflux or ulcers, such as antacids and cimetidine
- medicines to treat epilepsy (fits and convulsions), such as carbamazepine
- certain oral contraceptives (containing oestrogen)
- disulfiram, a medicine used in alcohol abuse
- some medicines used to treat Parkinson's disease, e.g. levodopa
- some treatments for tuberculosis, such as rifampin and isoniazid
- zidovudine, to treat HIV virus

These medicines may be affected by ARROW - DIAZEPAM or may affect how well ARROW - DIAZEPAM works. You may need different amounts of your medicines or you may need to take a different medicine. Your doctor can tell you what to do if you are taking any of these medicines.

If you are not sure whether you are taking any of these medicines, check with your doctor or pharmacist.

Your doctor or pharmacist has more information on these medicines, and on other medicines that you need to be careful with, or avoid while taking ARROW - DIAZEPAM.

How to take ARROW - DIAZEPAM properly

How much to take

Your doctor will tell you how much ARROW - DIAZEPAM you need to take each day. It is important that you take ARROW - DIAZEPAM only as directed by your doctor. Do not take more than the recommended dose.

The dose of ARROW - DIAZEPAM varies from patient to patient and will depend on your age, and the condition you are being treated for. Your doctor will prescribe the lowest dose that can control your symptoms.

For adults, the daily dose of ARROW - DIAZEPAM can vary between 2mg and 60mg daily, given in divided doses.

Elderly patients and patients with kidney or liver problems can be more susceptible to the risk of side effects and therefore lower dosages are generally recommended.

Swallow the tablets whole with a glass of water. The tablets may be taken with or without food.

If you do not understand the instructions printed on the label, ask your doctor or pharmacist for help.

How long to take it

Take ARROW - DIAZEPAM only for as long as your doctor recommends.

ARROW - DIAZEPAM should only be taken for short periods of time (2-4 weeks) and at the lowest dose that can control your symptoms.

Continuous long-term use is not recommended, unless advised by your doctor. The use of ARROW - DIAZEPAM may lead to dependence of the medicine.

Development of dependence is common with regular use of benzodiazepines.

Abrupt discontinuation may lead to withdrawal symptoms. Discuss with your doctor a discontinuation schedule (tapering of your dosage) when you are to stop the medicine.

Withdrawal symptoms include the following effects:

- anxiety
- depression
- impaired concentration
- insomnia
- headache
- dizziness
- ringing in the ears
- loss of appetite
- tremor (shaking)
- perspiration
- irritability
- abnormal taste
- nausea, vomiting, abdominal cramps
- feeling faint when standing up

Do not be alarmed by this list, as if you taper your dosage as instructed by your doctor you will probably not suffer from any of these effects.

If you forget a dose

Do not take more than one dose at a time to make up for missed doses.

If you forget a dose, just take the next dose when it is due.

Taking your medicine at the same time each day may help you to remember to take it regularly.

While you are taking ARROW - DIAZEPAM

It is important that you take ARROW - DIAZEPAM exactly as prescribed. Taking more than the prescribed amount of ARROW - DIAZEPAM can increase the chance of developing unwanted side effects.

Things you must do

Before starting any new medicine, tell your doctor or pharmacist that you are taking ARROW - DIAZEPAM.

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

If you are going to have surgery, including dental surgery, tell your doctor or dentist that you are taking ARROW - DIAZEPAM.

If you become pregnant while taking ARROW - DIAZEPAM, tell your doctor immediately.

Tell your doctor if, for any reason, you have not taken your medicine exactly as directed.

Otherwise, your doctor may think that it is not working and change your treatment unnecessarily.

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

Things you must not do

Do not stop taking ARROW - DIAZEPAM or change the dose, without first checking with your doctor.

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

Do not use ARROW - DIAZEPAM to treat any other complaints unless your doctor tells you to.

Things to be careful of

Be careful driving or operating machinery until you know how ARROW - DIAZEPAM tablets affect you.

ARROW - DIAZEPAM can cause drowsiness, dizziness or loss of concentration in some people. It is therefore important that you make sure you know how you react to ARROW - DIAZEPAM before you drive a car, operate machinery, or do anything else that could be dangerous if you are dizzy or light headed.

Be careful drinking alcohol while taking ARROW - DIAZEPAM.

Drinking alcohol while you are taking ARROW - DIAZEPAM can make you drowsy or dizzy. Your doctor may therefore suggest that you avoid alcohol, while you are taking ARROW - DIAZEPAM.

Side effects

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

Like all medicines, ARROW - DIAZEPAM can have some unwanted 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.

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

- drowsiness
- loss of balance
- uncoordinated movement
- confusion
- headache
- stomach upsets
- skin rashes
- blurry or distorted vision
- difficulty urinating
- changes in sex drive
- suicidal thoughts
- forgetfulness, amnesia
- confusion
- agitation or aggression
- sleep disturbance, restlessness or irritability

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

- swelling of the face, lips, mouth or throat which may cause difficulty in swallowing or breathing
- severe confusion, drowsiness, loss of reflexes or muscle weakness
- yellowing of the skin and eyes
- hallucinations or delusions

The side effects listed above are rare but can be very serious. If you experience any of them, you may have had a severe allergic reaction to ARROW - DIAZEPAM so you may need urgent medical attention.

All of these side effects are very rare.

If you should suffer from any of these side effects or other undesired effect, tell your doctor or pharmacist.

This list of possible side effects is not complete. Other effects may occur in some people.

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

In case of overdose

You should only take the number of tablets that you have been told.

If you take too much ARROW - DIAZEPAM, the effects of the medication will be increased. You may feel extremely drowsy, have difficulty breathing, experience muscle weakness or become unconscious.

Immediately contact your doctor or the National Poisons Information Centre (0800 POISON or 0800 764 766) or go to the Emergency department at your nearest hospital, if you think that you may have taken too much, or if anyone else has taken any ARROW - DIAZEPAM by mistake. Do this even if there are no signs of discomfort or poisoning. You may need urgent medical attention. Take the container of ARROW - DIAZEPAM with you if you can.

Keep telephone numbers for these places handy.

Storage conditions

Keep ARROW - DIAZEPAM 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 ARROW - DIAZEPAM in a cool dry place where the temperature stays below 30°C, and protect from light.

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

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

Do not store ARROW - DIAZEPAM or other medicines in the bathroom or near a sink. Do not leave the tablets in the car or on window sills. Heat, light and dampness can destroy some medicines.

Disposal

If your doctor tells you to stop taking ARROW - DIAZEPAM or if the tablets have passed the expiry date, ask your pharmacist what to do with the remaining medicine.

Product Description

What ARROW - DIAZEPAM tablets look like

ARROW - DIAZEPAM comes in two strengths of tablets:

- ARROW - DIAZEPAM 2 is a white, round, flat-bevel edged tablet embossed with 'D2' on one side and breakline on the other.
- ARROW - DIAZEPAM 5 is a yellow, round, flat-bevel edged tablet embossed with 'D5' on one side and breakline on the other.

ARROW - DIAZEPAM is available in blisters packs of 50 tablets, and bottles of 200 or 500 tablets.

Ingredients

The active ingredient in ARROW - DIAZEPAM is diazepam:

- ARROW - DIAZEPAM 2 each tablet contains 2 mg of diazepam
- ARROW - DIAZEPAM 5 each tablet contains 5 mg of diazepam.

The tablets also contain

- lactose
- maize starch
- magnesium stearate
- quinoline yellow CI47005 (E104) (5 mg only).

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

Supplier

ARROW - DIAZEPAM is distributed in New Zealand by:

Teva Pharma (New Zealand) Limited
PO Box 128 244
Remuera
Auckland 1541
Telephone: 0800 800 097

Date of information

4 May 2107