Consumer Medicine Information (CMI) summary

The <u>full CMI</u> on the next page has more details. If you are worried about using this medicine, speak to your doctor or pharmacist.

1. Why am I using Arrow - Diazepam?

Arrow - Diazepam contains the active ingredient diazepam. Arrow - Diazepam is used for anxiety, to relax muscles, to treat trembling, confusional states or anxiety associated with alcohol withdrawal, and to treat panic attacks. It is also used to treat some types of epilepsy. In children, Arrow - Diazepam can be used to treat night terrors and sleepwalking. For more information, see Section <u>1. Why am I using Arrow - Diazepam?</u> in the full CMI.

2. What should I know before I use Arrow - Diazepam?

Do not use if you have ever had an allergic reaction to Arrow - Diazepam, any other benzodiazepine medicine, or any of the ingredients listed at the end of the CMI. The use of Arrow - Diazepam may lead to dependence on the medicine. **Talk to your doctor if you have any other medical conditions, have drug or alcohol addiction, drink alcohol, take any other medicines, or are pregnant or plan to become pregnant or are breastfeeding**. For more information, see Section <u>2. What should I know</u> <u>before I use Arrow - Diazepam?</u> in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with Arrow - Diazepam and affect how it works. A list of these medicines is in Section <u>3. What if</u> <u>1 am taking other medicines</u>? in the full CMI.

4. How do I use Arrow - Diazepam?

- Take Arrow Diazepam exactly as your doctor has prescribed. Your doctor will tell you how many Arrow Diazepam tablets to take each day.
- The usual adult dose is between 2 and 60 mg daily. Children, elderly and very ill patients may need to take less.
- Arrow Diazepam should be taken for short periods only (for example, 2-4 weeks), unless advised by your doctor.

More instructions can be found in Section <u>4. How do I use Arrow - Diazepam?</u> in the full CMI.

5. What should I know while using Arrow - Diazepam?

Things you should do	 Remind any doctor, dentist or pharmacist you visit that you are using Arrow - Diazepam. Do not take any other medicines without first telling your doctor. Call your doctor straight away if you become pregnant while taking Arrow - Diazepam. 	
Things you should not do	 Do not take Arrow - Diazepam for a longer time than your doctor has prescribed. Do not stop taking Arrow - Diazepam or lower the dose without first checking with your doctor, especially if you have epilepsy. Do not let yourself run out of medicine over the weekend or on holidays. 	
Driving or using machines	• Do not drive or operate machinery until you know how Arrow - Diazepam affects you.	
Drinking alcohol	• Alcohol may increase the effects of Arrow - Diazepam. Your doctor may suggest that you avoid alcohol or reduce the amount of alcohol you drink while you are using Arrow - Diazepam.	
Looking after your medicine	 Store below 30°C. Store in a cool, dry place away from young children. 	

For more information, see Section 5. What should I know while using Arrow - Diazepam? in the full CMI.

6. Are there any side effects?

Call your doctor straight away or go straight to the Emergency Department at your nearest hospital if you notice any of the following serious side effects: sudden anxiety or excitation, restlessness, agitation, irritability, anger, abnormal behaviour, hallucinations, delusions, severe sleep disturbances, thoughts of harming yourself or thoughts of suicide. Difficulties in breathing, choking or coughing. Speak to your doctor if you have any of the following less serious side effects and they worry you: drowsiness, tiredness, dizziness, unsteadiness, loss of memory, inattentiveness, confusion, lack of concentration, headache, hangover feeling in the morning, slurred speech, or unpleasant dreams. For more information, including what to do if you have any side effects, see Section <u>6. Are there any side effects?</u> in the full CMI.

Arrow - Diazepam

Active ingredient: Diazepam

Consumer Medicine Information (CMI)

This leaflet provides important information about using Arrow - Diazepam. You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about using Arrow -Diazepam.

Where to find information in this leaflet:

- 1. Why am I using Arrow Diazepam?
- 2. What should I know before I use Arrow Diazepam?
- 3. What if I am taking other medicines?
- 4. How do I use Arrow Diazepam?
- 5. What should I know while using Arrow Diazepam?
- 6. Are there any side effects?
- 7. Product details

1. Why am I using Arrow - Diazepam?

Arrow - Diazepam contains the active ingredient diazepam. Arrow - Diazepam belongs to a group of medicines called benzodiazepines, which are thought to work by their action 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 tablets for another reason.

2. What should I know before I use Arrow -Diazepam?

Warnings

Do not use Arrow - Diazepam if:

- you are allergic to diazepam, any other benzodiazepine medicine, or any of the 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
- you have myasthenia gravis
- you or your child have problems swallowing
- you have an acute closed-angle glaucoma (increased pressure in the eye)
- you or your child have attention deficit disorder (ADD)

Tell your doctor if you drink alcohol. Alcohol may increase the effects of Arrow - Diazepam. It is not recommended to drink alcohol while you are taking Arrow - Diazepam.

Check with your doctor if you:

- have any other medical conditions, including:
 - o liver, kidney or lung disease
 - high or low blood pressure
 - o glaucoma (high pressure in the eye)
 - suicidal thoughts, depression, schizophrenia or other mental illness
 - o epilepsy (fits)
 - history of alcohol or drug abuse
 - take any medicines for any other condition
- are allergic to any other medicines, foods, dyes or preservatives.

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them. See additional information under Section <u>6. Are there any side effects?</u>

Pregnancy and breastfeeding

Check with your doctor if you are pregnant or intend to become pregnant.

If there is a need to take Arrow - Diazepam when you are pregnant your doctor will discuss the risks and benefits to you and the unborn baby. There may be an increased risk of miscarriage from benzodiazepine exposure during pregnancy.

Talk to your doctor if you are breastfeeding or intend to breastfeed.

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

Use in children

• Do not give Arrow - Diazepam to children under the age of six months.

Dependence

• The use of benzodiazepines (such as Arrow -Diazepam) may lead to dependence on the medicine.

3. What if I am taking other medicines?

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

Some medicines may interfere with Arrow - Diazepam and affect how it works, and some medicines may be affected by Arrow - Diazepam. These medicines include:

- other sleeping tablets, sedatives or tranquillisers
- medicines to treat depression or mental illness
- medicines to treat epilepsy (fits and convulsions), such as carbamazepine, phenobarbital, phenytoin
- pain relievers
- muscle relaxants
- cimetidine and omeprazole- medicines used to treat ulcers
- disulfiram a medicine used in alcohol abuse
- some medicines to treat Parkinson's disease e.g. levodopa
- some treatments for tuberculosis, such as rifampin and isoniazid
- theophylline, a medicine used to treat chronic obstructive pulmonary disease and asthma
- cisapride a medicine used to treat gastric reflux
- certain medicines used to treat fungal infections such as fluconazole, itraconazole, ketoconazole
- antiviral agents used to treat HIV
- certain oral contraceptives

Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect Arrow - Diazepam.

4. How do I use Arrow - Diazepam?

How much to take

 Take Arrow - Diazepam exactly as your doctor has prescribed. Your doctor will tell you how many Arrow -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 2 and 60 mg daily, given in divided doses. Children, elderly and very ill patients may need to take less.
- Arrow Diazepam should be taken for short periods only (for example, 2-4 weeks) and at the lowest dose that can control your symptoms. Continuous longterm use is not recommended unless advised by your doctor.
- Follow the instructions provided and take Arrow-Diazepam until your doctor tells you to stop.

When to take Arrow - Diazepam

• Arrow - Diazepam can be taken up to three times a day. Your doctor will tell you how much you need to take.

How to take Arrow - Diazepam

- Tablets should be swallowed whole with a glass of water.
- Tablets can be taken with or without food.
- Tablets can be divided into equal doses.

If you forget to use Arrow - Diazepam

Arrow - Diazepam should be used regularly at the same time each day.

If it is almost time for your next dose, skip the dose you missed and take your next dose when you are meant to.

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

If you use too much Arrow - Diazepam

If you think that you have used too much Arrow -Diazepam, you may need urgent medical attention. If you have taken too much Arrow - Diazepam, you may feel drowsy, tired, confused, dizzy, have difficulty breathing, feel weak or become unconscious.

You should immediately:

- phone the National Poisons Centre on 0800 POISON (0800 764766), or
- contact your doctor, or
- go to the Emergency Department at your nearest hospital.

You should do this even if there are no signs of discomfort or poisoning.

5. What should I know while using Arrow - Diazepam?

Things you should do

Tell all doctors, dentists and pharmacists who are treating you that you are taking Arrow - Diazepam.

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

Call your doctor straight away if you:

- become pregnant while taking Arrow Diazepam
- have not taken your medicine exactly as prescribed
- 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.

Remind any doctor, dentist or pharmacist you visit that you are using Arrow - Diazepam.

Things you should not do

- Do not take Arrow Diazepam for a longer time than your doctor has prescribed. Arrow Diazepam should be taken for short periods only (for example, 2-4 weeks) unless advised by your doctor.
- Do not stop taking Arrow 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 Arrow - 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 Arrow Diazepam if you suffer from epilepsy. Stopping this medicine suddenly may make your epilepsy worse.
- Do not give Arrow Diazepam to anyone else even if their symptoms seem similar to yours.
- Do not use Arrow Diazepam to treat other complaints unless your doctor says to.

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.

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

Driving or using machines

Do not drive or use any machines or tools until you know how Arrow - Diazepam affects you.

Arrow - Diazepam may cause drowsiness or dizziness in some people and therefore may affect alertness. Make sure you know how you react to Arrow - 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.

Drinking alcohol

Tell your doctor if you drink alcohol. Alcohol may increase the effects of Arrow - Diazepam. It is not recommended to drink alcohol while you are taking Arrow - Diazepam.

Looking after your medicine

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

Follow the instructions in the carton on how to take care of your medicine properly.

Store it in a cool dry place where the temperature stays below 30°C, away from moisture, heat or sunlight; for example, do not store it:

- in the bathroom or near a sink, or
- in the car or on window sills.

Keep it where young children cannot reach it.

Getting rid of any unwanted medicine

If you no longer need to use this medicine or it is out of date, take it to any pharmacy for safe disposal.

Do not use this medicine after the expiry date.

6. Are there any side effects?

All medicines can have side effects. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention.

See the information below and, if you need to, ask your doctor or pharmacist if you have any further questions about side effects.

Less serious side effects

Less serious side effects	What to do
Neurological or brain-related: • drowsiness, tiredness • dizziness, unsteadiness • loss of memory, inattentiveness, confusion, lack of concentration • uncoordinated movement • headache, hangover feeling in the morning • slurred speech • unpleasant dreams • blurry or distorted vision • changes in sex drive	Speak to your doctor if you have any of these less serious side effects and they worry you.
 Skin related: itching or skin rash Gastrointestinal related: stomach upset 	

Serious side effects

Serious side effects	What to do
 Immune system disorders swelling of the face, lips, mouth or throat which may cause difficulty in swallowing or breathing 	Call your doctor straight away, or go straight to the Emergency Department at
Neurological or brain-related:	your nearest
sudden anxiety or excitation	hospital if you notice any of

 restlessness, agitation, 	these serious
irritability, anger, abnormal	side effects.
behaviour	
• severe confusion, drowsiness,	
loss of reflexes or muscle	
weakness	
hallucinations or delusions	
 severe sleep disturbances 	
 thoughts of harming yourself or 	
thoughts of suicide	
Liver or cell blodder veleted	
Liver or gall bladder related	
 yellowing of the skin and eyes 	
Renal and urinary disorders	
 difficulty urinating 	
Respiratory or breathing-related:	
 Difficulties in breathing or 	
choking or coughing	

Tell your doctor or pharmacist if you notice anything else that may be making you feel unwell.

Other side effects not listed here may occur in some people.

Reporting side effects

After you have received medical advice for any side effects you experience, you can report side effects to <u>https://pophealth.my.site.com/carmreportnz/s/</u>. By

reporting side effects, you can help provide more information on the safety of this medicine.

Always make sure you speak to your doctor or pharmacist before you decide to stop taking any of your medicines.

7. Product details

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

What Arrow - Diazepam contains

Active ingredient	Diazepam
(main ingredient)	
Other ingredients	ARROW – DIAZEPAM 2 mg
(inactive ingredients)	Lactose, magnesium stearate, maize starch
	ARROW – DIAZEPAM 5 mg
	Lactose, magnesium stearate, maize starch, quinoline yellow.
Potential allergens	Contains lactose
	Arrow - Diazepam tablets are gluten-free.

Do not take this medicine if you are allergic to any of these ingredients.

What Arrow - Diazepam looks like

Arrow - Diazepam 2mg tablets are white, round, flat-bevel edged tablets embossed with 'D2' on one side and breakline on the other side.

Arrow - Diazepam 5mg tablets are yellow, round, flat-bevel edged tablets embossed with 'D5' on one side and breakline on the other side.

Arrow - Diazepam comes in blisters packs of 50 tablets and bottles of 200 and 500 tablets

This product may not be interchangeable with other products containing this ingredient in the New Zealand's market.

Who distributes Arrow - Diazepam

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

This leaflet was prepared in January 2025.