

# NEW ZEALAND CONSUMER MEDICINE INFORMATION

## MYLAN MIDAZOLAM

*Midazolam 1 mg/mL and 5 mg/mL ampoules*



### What is in this leaflet

This leaflet answers some common questions about MYLAN MIDAZOLAM.

It does not contain all the available information. It does not take the place of talking to your doctor or pharmacist.

All medicines have risks and benefits. Your doctor has weighed the risks of you taking MYLAN MIDAZOLAM against the benefits they expect it will have for you.

**If you have any concerns about being given this medicine, ask your doctor or pharmacist.**

**Keep this leaflet.** You may need to read it again.

### What MYLAN MIDAZOLAM is used for

MYLAN MIDAZOLAM is used for the following.

- may be given as a sedative during some short medical procedures.
- may be given before an operation to produce sleepiness or drowsiness and to relieve anxiety. It may also be used in combination with other anaesthetic agents to keep you asleep during an operation.
- If you are in an intensive care unit, you may receive MYLAN MIDAZOLAM as a sedative.

This medicine belongs to a group of medicines called benzodiazepines. They are thought to work by their action on brain chemicals.

MYLAN MIDAZOLAM can cause sedation (sleepiness), short term amnesia (no memory of events around the time you are given MYLAN MIDAZOLAM, and/or anaesthesia (heavy sleep for surgery) depending on the dose you are given.

**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.

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

### Before you are given MYLAN MIDAZOLAM

#### *When you must not use it*

**Do not have MYLAN MIDAZOLAM if you have an allergy to:**

- any medicine containing midazolam or any other benzodiazepine medicine.
- any of the ingredients listed at the end of this leaflet.
- Some of the 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.

**If you are not sure whether you should be given this medicine, talk to your doctor.**

#### *Before you use it*

**Tell your doctor if you have allergies to any other medicines, foods, preservatives or dyes.**

**Tell your doctor if you have or have had any of the following medical conditions:**

- liver, kidney, heart or lung disease
- breathing difficulties including sleep apnoea
- any long-term illness that is making you weak
- history of alcohol or drug abuse
- you have severe muscle weakness, known as myasthenia gravis
- mental disorders including; depression, psychosis or schizophrenia
- epilepsy (fits or convulsions)

**Tell your doctor if you are taking opioids, a class of medicines used to treat pain.** Opioids include medicines such as oxycodone, fentanyl, hydromorphone, tramadol and taking them at the same time as MYLAN MIDAZOLAM has the potential to cause very serious side effects.

**Tell your doctor if you are pregnant or plan to become pregnant or are breast-feeding.** Your doctor can discuss with you the risks and benefits involved.

**If you have not told your doctor about any of the above, tell him/her before you receive MYLAN MIDAZOLAM.**

#### *Dependency*

MYLAN MIDAZOLAM can cause physical dependency, especially if you have a history of alcohol or drug abuse, when used long-term (for example, when used in an intensive care unit for long periods of time). Your dose may be reduced gradually to overcome this effect.

#### *Taking other medicines*

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

Some medicines and MYLAN MIDAZOLAM may interfere with each other. These include:

- erythromycin, clarithromycin and rifampicin which are antibiotics
- sodium valproate, an epilepsy medicine
- ketoconazole, voriconazole, fluconazole and itraconazole, antifungal medicines
- saquinavir and other HIV/AIDS medicines
- boceprevir and telaprevir, Hepatitis C medicines
- cimetidine and ranitidine, medicines used to treat ulcers and indigestion
- opioids
- ticagrelor, a medicine used to lower your risk of stroke

These medicines may be affected by MYLAN MIDAZOLAM 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.

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## How MYLAN MIDAZOLAM is given

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### *How much is given*

MYLAN MIDAZOLAM solution for injection may be given to you as an injection into a vein or muscle, or as an infusion into a vein. Other medications may also be given at the same time.

In children MYLAN MIDAZOLAM solution for injection can also be given as drops into the mouth or nose, or rectally (into the back passage) using a syringe without a needle.

Your doctor will adjust the dose necessary for you. This depends on which medical procedure you are having, your age, weight, general health, and the way in which the medicine is being given to you.

### *How long is it given*

MYLAN MIDAZOLAM may be given before, during or after a medical procedure, or continuously for patients in an intensive care unit.

### *If you use too much (overdose)*

**Immediately telephone your doctor or the National Poisons Information Centre (0800 POISON or 0800 764 766) for advice, or go to Accident and Emergency at the nearest hospital, if you think that you or anyone else may have taken too much MYLAN MIDAZOLAM. Do this even if there are no signs of discomfort or poisoning.**

You may need urgent medical attention.

Symptoms of an overdose may include feeling sick (nausea), vomiting, dizziness, slowing of breathing, slowing of heart rate, drowsiness, confusion, loss of muscle tone and coordination, tiredness, loss of muscle tone and coordination, difficulty in speaking, uncontrollable eye movements, loss of normal reflexes and coma. A few people may become over-excited and/or angry.

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

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## While you are having MYLAN MIDAZOLAM

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### *Things you must do*

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

**Tell your doctor if you feel MYLAN MIDAZOLAM is not helping you.**

### *Things you must not do*

**Do not drive or operate machinery until you know how MYLAN MIDAZOLAM affects you.** MYLAN MIDAZOLAM may cause drowsiness, dizziness, fatigue, confusion, hallucinations and forgetfulness and therefore may affect alertness. Make sure you know how you react to MYLAN MIDAZOLAM before you drive a car or operate machinery, or do anything else that could be dangerous if you are drowsy, dizzy or not alert. If you have not had enough sleep or have been drinking alcohol, you are likely to be less alert.

### *Things to be careful of*

**Particular care should be taken 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.

If you drink alcohol these effects could be worse.

**Drinking alcohol is not recommended after you have been given MYLAN MIDAZOLAM.**

Ask your doctor or pharmacist how long you should avoid alcohol for.

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## Side effects

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**Tell your doctor or pharmacist as soon as possible if you do not feel well after you have received MYLAN MIDAZOLAM.**

This medicine may have unwanted side effects in a few people. All medicines can have side effects. Sometimes they are serious, most of the time they are not. You may need medical attention if you get some of the side effects.

If you are over 60 years of age you may have an increased chance of getting side effects. **Do not be alarmed by the following lists of side effects. You may not experience any of them.**

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

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

- drowsiness, tiredness
- dizziness, unsteadiness
- loss of memory, inattentiveness
- confusion, lack of concentration, feeling disorientated, restless or irritable
- mood changes
- anxiety, nightmares, hallucinations, inappropriate behaviour
- headache
- hiccups
- feeling sick with or without vomiting
- constipation
- dry mouth
- involuntary (uncontrollable) movements
- rash or itching
- redness or pain at the site of the injection
- older patients, and those taking other sedatives or alcohol may be more likely to fall and suffer fractures

**If any of the following happen, tell your doctor immediately or go to Accident and Emergency at your nearest hospital:**

- sudden anxiety or excitation
- feeling agitated, aggressive or angry
- hallucinations or delusions
- convulsions
- allergic reaction – sudden signs such as rash, itching or hives on the skin, swelling of the face, lips, tongue which may cause difficulty in swallowing or breathing and other parts of the body
- shortness of breath, wheezing or trouble breathing

The above list includes very serious side effects. You may need urgent medical attention or hospitalisation.

**Tell your doctor or pharmacist if you notice anything that is making you feel unwell.**

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## After taking MYLAN MIDAZOLAM

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### **Storage**

MYLAN MIDAZOLAM solution for injection will be stored in the pharmacy or on the ward out of reach of children. It is kept in a cool dry place where the temperature stays below 25°C. It should be protected from light.

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### **Product description**

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#### ***What it looks like***

MYLAN MIDAZOLAM solution for injection is a clear, colourless solution, packaged in a clear colourless ampoule.

#### ***Ingredients***

MYLAN MIDAZOLAM contains 5 mg/ 5 mL or 15 mg/ 3 mL of midazolam as the active ingredient.

It also contains:

- sodium chloride
- hydrochloric acid
- sodium hydroxide
- water for injection

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### **If you want to know more**

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Should you have any questions regarding this product, please contact your pharmacist or doctor.

#### ***Who supplies this medicine***

Distributed in New Zealand by:

Mylan New Zealand Ltd,  
PO Box 11183,  
Eilerslie,  
Auckland.

Telephone: (09) 579 2792

#### ***Date of Information***

27 June 2018  
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