

# Mogadon®

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## Consumer Medicine Information (CMI) summary

The [full CMI](#) 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 Mogadon?

Mogadon contains the active ingredient nitrazepam. Mogadon is used to treat sleeping problems, also called insomnia.

For more information, see Section [1. Why am I using Mogadon?](#) in the full CMI.

### 2. What should I know before I use Mogadon?

Do not use if you have ever had an allergic reaction to Mogadon, benzodiazepines, or any of the ingredients listed at the end of the CMI, have severe and chronic lung disease or severe liver disease.

**Talk to your doctor if you have any other medical conditions, take any other medicines, or are pregnant or plan to become pregnant or are breastfeeding, drink alcohol, or you have a history of falling or are unsteady when walking.**

For more information, see Section [2. What should I know before I use Mogadon?](#) in the full CMI.

### 3. What if I am taking other medicines?

Some medicines may interfere with Mogadon and affect how it works.

A list of these medicines is in Section [3. What if I am taking other medicines?](#) in the full CMI.

### 4. How do I use Mogadon?

- Usual adult dose is 1-2 tablets. For the elderly the usual dose is half to 1 tablet.
- Take Mogadon before going to bed.

More instructions can be found in Section [4. How do I use Mogadon?](#) in the full CMI.

### 5. What should I know while using Mogadon?

<b>Things you should do</b>	
	<ul style="list-style-type: none"><li>• Remind any doctor, dentist, mental health professional or pharmacist you visit that you are using Mogadon.</li><li>• Tell your doctor or a mental health professional immediately if you have any suicidal</li></ul>

	<p>thoughts or other mood changes.</p> <ul style="list-style-type: none"> <li>● If you become pregnant while you are taking Mogadon, tell your doctor immediately.</li> </ul>
<b>Things you should not do</b>	<ul style="list-style-type: none"> <li>● Do not stop using this medicine suddenly as you may experience unpleasant withdrawal symptoms, which may require medical attention.</li> <li>● Do not use Mogadon for longer than your doctor says.</li> </ul>
<b>Driving or using machines</b>	<ul style="list-style-type: none"> <li>● Do not drive or operate machinery until you know how Mogadon affects you.</li> <li>● Mogadon causes drowsiness and affects alertness in most people.</li> </ul>
<b>Drinking alcohol</b>	<ul style="list-style-type: none"> <li>● Do not drink alcohol whilst using Mogadon as alcohol may increase its effects.</li> </ul>

<b>Looking after your medicine</b>	<ul style="list-style-type: none"><li>• Store below 30°C in a cool dry place.</li><li>• Keep out of reach of children</li></ul>
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For more information, see Section [5. What should I know while using Mogadon?](#) in the full CMI.

## **6. Are there any side effects?**

Common side effects include drowsiness, dizziness, tiredness, confusion, unsteadiness when walking, memory impairment, headache, hangover feeling in the morning, slurred speech, clumsiness, numbed emotions, double vision, inattention, unpleasant dreams and rebound insomnia.

Serious side effects include swelling of the tongue or throat and difficulty in breathing. These side effects require urgent medical attention.

For more information, including what to do if you have any side effects, see Section [6. Are there any side effects?](#) in the full CMI.

# Mogadon®

**Active ingredient:** *Nitrazepam*

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## Consumer Medicine Information (CMI)

This leaflet provides important information about using Mogadon. **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 Mogadon**

**Where to find information in this leaflet:**

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

## 1. Why am I using Mogadon?

**Mogadon contains the active ingredient nitrazepam.** Mogadon is a benzodiazepine. It is thought to work by its action on brain chemicals.

**Mogadon is used to treat sleeping problems, also called insomnia.**

## **2. What should I know before I use Mogadon?**

### **Warnings**

#### **Do not use Mogadon if:**

- You are allergic to nitrazepam, other benzodiazepines such as diazepam, temazepam, oxazepam, alprazolam and clonazepam. or any of the ingredients listed at the end of this leaflet. Always check the ingredients to make sure you can use this medicine.
- You have severe and chronic lung disease (e.g., chronic obstructive airway disease) and have difficulty breathing.
- You have a severe liver disorder.

#### **Check with your doctor if you:**

- Take any other medicines for any other conditions
- Drink alcohol regularly. Alcohol may increase the effects of this medicine.
- Have a history of falling or are unsteady when walking

- Have any other medical conditions including:
  - liver, kidney, or lung disease
  - fits or convulsions
  - severe muscle weakness known as myasthenia gravis
  - high or low blood pressure
  - glaucoma (high pressure in the eye)
  - depression, psychosis, or schizophrenia.

Mogadon may increase depression in some people.

Severely disturbed schizophrenics may experience confusion and withdrawal.

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 [6. Are there any side effects?](#)

## **Pregnancy and breastfeeding**

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

Mogadon can cross the placenta and cause side effects in your unborn baby. Withdrawal symptoms have also been reported in newborn babies.

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

Mogadon passes into breast milk and may cause your baby to experience drowsiness and have feeding difficulties.

## Use in Children

Do not give this medicine to children unless advised by the child's doctor.

The safety and effectiveness of this medicine in children have not been established.

## Use in the Elderly

Elderly people may be more susceptible to the sedative effects of Mogadon and associated giddiness, unsteadiness, and confusion, which may increase the possibility of a fall.

### 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 Mogadon and affect how it works including:**

- medicines to control fits
- cimetidine, a medicine used to treat ulcers and reflux
- disulfiram, a medicine used to deter the consumption of alcohol.

**Medicines that may increase the effect of Mogadon include:**

- other sleeping tablets, sedatives, or tranquillisers

- medicines for depression
- medicines for allergies, e.g., antihistamines or cold tablets
- pain relievers
- muscle relaxants.

Taking Mogadon with these medicines may slow down your nervous system more than intended resulting in lethargy, breathing problems, dizziness, confusion, or problems with your vision.

Seek urgent medical attention if life-threatening symptoms such as breathing difficulties, inability to move or coma occur.

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

## **4. How do I use Mogadon?**

### **How much to take**

- The usual adult dose of Mogadon is 1-2 tablets.
- For the elderly, the usual dose is half to 1 tablet.
- Swallow Mogadon whole with a glass of water.
- Follow the instructions provided on the pack and use Mogadon until your doctor tells you to stop.

### **When to take Mogadon**

- Take Mogadon before going to bed.

- Do not use Mogadon for longer than your doctor says.

## **If you forget to use Mogadon**

Mogadon should be used regularly at the same time each day.

If you forget to take Mogadon before you go to bed and you wake up late in the night or early morning, do not take any Mogadon as you may have trouble waking in the morning. If you have any questions about this, ask your doctor or pharmacist.

## **If you use too much Mogadon**

If you think that you have used too much Mogadon, you may need urgent medical attention.

### **You should immediately:**

- phone the Poisons Information Centre (**by calling 13 11 26**), 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.**

If you take too much Mogadon mild symptoms include drowsiness, mental confusion, and lethargy. In more serious cases, symptoms include inability to move, loss of muscle tone, low blood pressure, breathing difficulties, coma and very rarely death.

## **5. What should I know while using Mogadon?**

### **Things you should do**

**Use Mogadon exactly as your doctor has prescribed.**

**Tell your doctor if you feel Mogadon is not helping your condition.**

**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.

**Call your doctor or mental health professional straight away if you:**

- Have any suicidal thoughts or other mood changes. All thoughts of suicide must be taken seriously.
- If you become pregnant while you are taking Mogadon.

**Tell your doctor if you notice any unusual changes in your sleep behaviour such as sleep walking, sleep driving or any other bizarre sleep-related behaviours.**

You may need medical attention if you experience these behaviours.

**Be careful when taking Mogadon if you are elderly, unwell, or taking other medicines.**

Some people may experience side effects such as drowsiness, confusion, dizziness, and unsteadiness. These may increase the risk of a fall.

Remind any doctor, mental health professional, dentist, or pharmacist you visit that you are using Mogadon.

## **Things you should not do**

**Do not take Mogadon for a longer time than your doctor has prescribed.**

Mogadon is usually 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.

**Do not stop using this medicine suddenly or change your dose without first checking with your doctor.**

Your doctor will slowly reduce your dose of Mogadon before you can stop taking it completely.

Stopping this medicine suddenly may cause some unwanted effects including:

- insomnia
- dizziness
- anxiety or panic attacks
- feeling dissatisfied with life
- feeling 'outside of your body' or a sense of unreality
- delusional beliefs
- palpitations
- involuntary movements

- extra sensitive to light, sound, and touch
- abnormal body sensations (e.g., feeling of motion, metallic taste)
- short-term memory loss.

In severe cases you may experience:

- convulsions
- tremor
- abdominal and muscle cramps
- confusion
- delirium, hallucinations, or psychosis
- high temperature or sweating
- vomiting.

**Do not suddenly stop taking Mogadon if you suffer from epilepsy.**

Stopping this medicine suddenly may make your epilepsy worse.

**Do not use this medicine to treat any other complaints unless your doctor says to.**

**Do not give Mogadon to anyone else, even if their symptoms seem similar to yours.**

## **Driving or using machines**

**Do not drive or use any machines or tools until you know how Mogadon affects you.**

Mogadon causes drowsiness and affects alertness in most people.

Make sure you know how you react to Mogadon before you drive a car, operate machinery, or do anything else that could be dangerous if you are drowsy, dizzy, or not alert.

Even if you take Mogadon at night, you may still be drowsy or dizzy the next day.

## **Drinking alcohol**

### **Tell your doctor if you drink alcohol.**

Combining Mogadon and alcohol can make you more sleepy, dizzy, lightheaded or increase the risk of sleep disorders.

Your doctor may suggest that you avoid alcohol or reduce the amount of alcohol you drink while you are taking Mogadon.

## **Looking after your medicine**

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

- Keep your tablets in their blister pack until it is time to take them.
- Store below 30°C and protect from light.

Store it in a cool dry place 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 windowsills.

**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
<ul style="list-style-type: none"><li>• drowsiness</li><li>• dizziness</li><li>• fatigue</li><li>• confusion</li><li>• unsteadiness when walking</li><li>• impairment of memory</li><li>• headache</li><li>• hangover feeling in the morning</li></ul>	<p><b>Speak to your doctor if you have any of these less serious side effects and they worry you.</b></p>

<b>Less serious side effects</b>	<b>What to do</b>
<ul style="list-style-type: none"> <li>● slurred speech</li> <li>● clumsiness, lack of coordination, numbed emotions</li> <li>● reduced alertness</li> <li>● muscle weakness</li> <li>● double vision</li> <li>● inattention</li> <li>● unpleasant dreams</li> <li>● rebound insomnia.</li> </ul>	

## **Serious side effects**

<b>Serious side effects</b>	<b>What to do</b>
<p><b>Allergic reactions:</b></p> <ul style="list-style-type: none"> <li>● swelling of the tongue or throat</li> <li>● difficulty in breathing.</li> </ul>	<p><b>Call your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you notice any of these serious side effects.</b></p>

**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 the Therapeutic Goods Administration online at [www.tga.gov.au/reporting-problems](http://www.tga.gov.au/reporting-problems). 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 Mogadon contains

<b>Active ingredient (main ingredient)</b>	Nitrazepam 5 mg
<b>Other ingredients (inactive ingredients)</b>	Lactose Maize starch Magnesium stearate
<b>Potential allergens</b>	Lactose

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

Mogadon does not contain gluten, sucrose, tartrazine, or any other azo dyes.

## **What Mogadon looks like**

Mogadon tablets are white, marked ICN on the upper face and a single break bar on the lower face.

Mogadon comes in a blister pack containing 25 tablets.

Registration number: AUST R 13751.

## **Who distributes Mogadon**

iNova Pharmaceuticals (Australia) Pty Limited

ABN: 13 617 871 539

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