

Consumer Medicine Information (CMI) summary

The [full CMI](#) on the next page has more details. If you are worried about taking this medicine, speak to your doctor or pharmacist.

1. Why am I taking ALODORM?

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

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

2. What should I know before I take ALODORM?

Do not use if you have ever had an allergic reaction to nitrazepam, benzodiazapines 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, are pregnant or plan to become pregnant or are breastfeeding, or you have a history of falling or are unsteady when walking.

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

3. What if I am taking other medicines?

Some medicines may interfere with ALODORM 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 take ALODORM?

- Follow all directions given to you by your doctor. Usual adult dose is 1-2 tablets. For the elderly the usual dose is half to 1 tablet.
- Take ALODORM before going to bed.

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

5. What should I know while taking ALODORM?

Things you should do	- Remind any doctor, dentist or pharmacist you visit that you are taking ALODORM. - Tell your doctor or a mental health professional immediately if you have any suicidal thoughts or other mood changes. - If you become pregnant while you are taking ALODORM, tell your doctor immediately.
Things you should not do	- Do not stop taking this medicine suddenly as you may experience unpleasant withdrawal symptoms, which may require medical attention. - Do not take ALODORM for longer than your doctor says.
Driving or using machines	- Do not drive or operate machinery until you know how ALODORM affects you. - ALODORM causes drowsiness and affects alertness in most people.
Drinking alcohol	Do not drink alcohol whilst taking ALODORM as alcohol may increase its effects.
Looking after your medicine	- Store below 25°C in a cool dry place. Protect from light. - Keep out of reach of children.

For more information, see Section [5. What should I know while taking ALODORM?](#) in the full CMI.

6. Are there any side effects?

Less serious side effects: 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.

Very serious side effects: 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.

ALODORM™

Active ingredient(s): nitrazepam

Consumer Medicine Information (CMI)

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

Where to find information in this leaflet:

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

1. Why am I taking ALODORM?

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

ALODORM is used to treat sleeping problems, also called insomnia.

Your doctor may have prescribed ALODORM for another reason.

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

2. What should I know before I take ALODORM?

Warnings

Do not take ALODORM 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.
 - Some of the symptoms of an allergic reaction may include skin rash, itching or hives; swelling of the face, lips or tongue which may cause difficulty in swallowing or breathing; wheezing or shortness of breath.

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.
- the expiry date printed on the pack has passed or if the packaging is torn or shows signs of tampering.

Check with your doctor if you:

- take any 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
 - epilepsy, fits or convulsions
 - severe muscle weakness known as myasthenia gravis
 - high or low blood pressure
 - glaucoma (increased pressure in the eye)
 - depression, psychosis, or schizophrenia.

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

- plan to have surgery.

If you have not told your doctor about any of the above, tell them before you start taking ALODORM.

ALODORM 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.

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

Your doctor will discuss the risks and benefits of taking ALODORM during pregnancy.

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

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

Your doctor will discuss the risks and benefits of taking ALODORM when breastfeeding.

Use in Children

ALODORM is not recommended for 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 ALODORM 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 ALODORM and affect how it works. These include:

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

Medicines that may increase the effect of ALODORM include:

- other sleeping tablets, sedatives, or tranquillisers
- medicines for depression
- medicines for allergies, colds or travel sickness e.g. antihistamines or cold tablets
- pain relievers such as opioid medicines
- muscle relaxants.

Taking ALODORM 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 ALODORM.

You may need to take different amounts of your medicine or you may need to take different medicines.

Your doctor can tell you what to do if you are taking any of these medicines.

Your doctor and pharmacist have more information on medicines to be careful with or avoid while taking ALODORM.

4. How do I take ALODORM?

How much to take

The dose may vary from person to person. Your doctor will tell you how many tablets you need to take each day.

- The usual adult dose of ALODORM is 1-2 tablets.
- For the elderly, the usual dose is half to 1 tablet.
- Swallow ALODORM whole with a glass of water.
- Follow the instructions given to you by your doctor and pharmacist carefully and take ALODORM until your doctor tells you to stop.

They may differ from the information contained in this leaflet. If you do not understand the instructions on the label, ask your doctor or pharmacist.

When to take ALODORM

- Take ALODORM before going to bed.
- Do not take ALODORM for longer than your doctor says.

If you forget to take ALODORM

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

If you take too much ALODORM

If you think you or anyone else have taken too much ALODORM, urgent medical attention may be needed.

You should immediately:

- phone the Poisons Information Centre (telephone 13 11 26) for advice, 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.

Also report if any other medicines or alcohol has been taken.

If you take too much ALODORM 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 taking ALODORM?

Things you should do

- **Take ALODORM exactly as your doctor has prescribed.**

If you plan to have surgery that requires a general anaesthetic, tell your doctor or dentist that you are taking ALODORM.

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

- **Tell your doctor if you feel ALODORM 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.
- Visit your doctor regularly. Your doctor needs to check your progress to see whether you need to keep taking ALODORM. You may also need to have tests to check your blood and liver function.

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 ALODORM.

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 should not take ALODORM and may need medical attention if you experience these behaviours.

Be careful when taking ALODORM 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 taking ALODORM.

Things you should not do

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

ALODORM 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.

Do not stop taking ALODORM suddenly or change your dose without first checking with your doctor.

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

Stopping ALODORM 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 ALODORM if you suffer from epilepsy.

Stopping ALODORM suddenly may make your epilepsy worse.

Do not take ALODORM to treat any other complaints unless your doctor says to.

Do not give ALODORM 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 ALODORM affects you.

This is very important if you are taking other drugs that also make you drowsy.

ALODORM causes drowsiness and affects alertness in most people, and may cause dizziness in some.

Make sure you know how you react to ALODORM 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 ALODORM at night, you may still be drowsy or dizzy the next day.

Things to be careful of

Some sleep medicines may cause short-term memory loss. When this occurs, a person may not remember what has happened for several hours after taking the medicine. This is usually not a problem since most people fall asleep after taking the medicine. To reduce this risk, ensure that you are able to get a full night's sleep (7 to 8 hours) before you need to be active again.

Drinking alcohol

Be careful drinking alcohol while taking ALODORM.

Tell your doctor if you drink alcohol.

Alcohol may increase the effects of ALODORM.

Combining ALODORM and alcohol can make you more sleepy, dizzy, lightheaded or increase the risk of sleep disorders. These include sleep-walking and some other related sleep behaviours such as sleep-driving, making phone calls or preparing and eating food whilst asleep.

This risk is also increased if you take more than the recommended dose.

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

Looking after your medicine

- Keep your tablets in bottle until it is time to take them.
- Store below 25°C. Protect from light.

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

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 window sills.

Keep it where young children cannot reach it.

A locked cupboard at least one-and-a-half metres above the ground is a good place to store medicines.

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 be serious and may need medical attention such as complex sleep behaviours.

Tell your doctor if you notice any unusual changes in your sleep behaviour or if you do not feel well while you are taking ALODORM.

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

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

Less serious side effects

Less serious side effects	What to do
• drowsiness • dizziness • fatigue • confusion • unsteadiness when walking • impairment of memory • headache • hangover feeling in the morning • slurred speech • clumsiness, lack of coordination • numbed emotions • reduced alertness • muscle weakness • double vision • inattention • unpleasant dreams • rebound insomnia.	Speak to your doctor if you have any of these less serious side effects and they worry you.

Very serious side effects

Very serious side effects	What to do
• swelling of the tongue or throat • difficulty in breathing.	Call your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you notice any of these very

Very serious side effects	What to do
	serious side effects.

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 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 ALODORM contains

Active ingredient (main ingredient)	Nitrazepam 5 mg
Other ingredients (inactive ingredients)	• lactose monohydrate • maize starch • pregelatinised maize starch • purified talc • colloidal anhydrous silica • magnesium stearate.
Potential allergens	Sugars as lactose and sulfites

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

Do not take this medicine if the packaging is torn or shows signs of tampering.

What ALODORM looks like

ALODORM is a 12 mm, flat bevel edged, white tablet marked "NM/5" on one side and "G" on the other.

(AUST R 54009)

Each bottle contains 25 tablets.

Who distributes ALODORM

Alphapharm Pty Ltd trading as Viatris

Level 1, 30 The Bond

30-34 Hickson Road

Millers Point NSW 2000

www.viatris.com.au

Phone: 1800 274 276

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