

NORMISON

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 NORMISON?

NORMISON contains the active ingredient temazepam. NORMISON is used to treat sleeping problems, also called insomnia. For more information, see Section [1. Why am I using NORMISON?](#) in the full CMI.

2. What should I know before I use NORMISON?

Do not use if you have ever had an allergic reaction to NORMISON or any of the ingredients listed at the end of the CMI.

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.

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

3. What if I am taking other medicines?

Some medicines may interfere with NORMISON 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 NORMISON?

- The dose of NORMISON varies from patient to patient.
- Your doctor will tell you how many tablets you need to take each day and when to take them.
- Swallow NORMISON with a glass of water. It can be taken with or without food.

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

5. What should I know while using NORMISON?

Things you should do	<ul style="list-style-type: none">• Remind any doctor, dentist or pharmacist you visit that you are using NORMISON.• Tell your doctor if you feel this medicine is not helping your condition.
Things you should not do	<ul style="list-style-type: none">• Do not stop taking your medicine or change the dose, without first checking with your doctor.• Do not take NORMISON for a longer time than your doctor has prescribed.
Driving or using machines	<ul style="list-style-type: none">• Do not drive or operate machinery until you know how NORMISON affects you• NORMISON may cause drowsiness or dizziness in some people.
Drinking alcohol	<ul style="list-style-type: none">• Be careful when drinking alcohol while taking NORMISON.• Combining NORMISON and alcohol can make you more sleepy, dizzy or light-headed.
Looking after your medicine	<ul style="list-style-type: none">• Keep your medicine in a cool dry place where the temperature stays below 30°C.• Keep your tablets in their blister pack until it is time to take them.• Keep it where children cannot reach it.

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

6. Are there any side effects?

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are taking NORMISON. Some mild side effects include dizziness, drowsiness, light-headedness, headache, nausea, stomach pain and dry mouth. Some serious side effects which may require medical attention include confusion, loss of memory, disorientation, behavioural or mood changes, signs of frequent infections such as fever, and yellowing of the eyes and skin (jaundice).

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.

NORMISON

Active ingredient: Temazepam

Consumer Medicine Information (CMI)

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

Where to find information in this leaflet:

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

1. Why am I using NORMISON?

NORMISON contains the active ingredient temazepam. NORMISON is a benzodiazepine which is thought to work by acting on the brain chemicals.

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

2. What should I know before I use NORMISON?

In general, benzodiazepines such as NORMISON should be taken for short periods only (for example 2 to 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.

Warnings

Do not use NORMISON if:

- You are allergic to Temazepam or any other benzodiazepine medicines 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 or breathing difficulties
- You have sleep apnoea
- You suffer from depression with or without anxiety problems. Temazepam can increase thoughts of death or suicide.
- The packaging shows signs of tampering or the tablets do not look quite right.
- If the expiry date (EXP) printed on the pack has passed.

Check with your doctor if you:

- have any medical conditions, especially the following:
 - liver, kidney or lung problems
 - epilepsy, fits or convulsions
 - severe muscle weakness known as myasthenia gravis
 - low blood pressure as it may lead to heart or brain complications.
 - any blood disorder
 - glaucoma (increased pressure in the eye)
 - depression, psychosis or schizophrenia
 - drug or alcohol dependence or a past history of these problems.
- take any medicines for any other condition
- if you are allergic to any other medicines, foods, dyes or preservatives
- if you plan to have surgery.

NORMISON is not recommended for use in children under 16 years of age, as its safety and effectiveness have not been established in this age group.

Suddenly stopping NORMISON in patients with epilepsy can cause a temporary increase in the number and severity of seizures.

Your doctor may have prescribed NORMISON for depression or psychosis. NORMISON is not recommended as the first choice of treatment for depression and psychosis. It may increase depression, worsen mental illness, suicidal thoughts and actions.

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.

NORMISON should not be used during pregnancy.

It should be avoided during the first trimester of pregnancy as it may increase the risk of defects present at birth.

It may cause unwanted effects in the newborn baby if taken during the late phase of pregnancy or during childbirth, such as low muscle strength, shallow breathing and feeding problems.

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

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

NORMISON may pass into breast milk and cause drowsiness and feeding difficulties in the baby. Your

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

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 NORMISON and affect how it works. These include:

- Other sleeping tablets, sedatives or tranquillisers
- Medicines for depression, schizophrenia and other mental illnesses
- Medicines to treat epilepsy and fits
- Medicines for allergies, for example antihistamines or cold tablets
- Medicines used to treat Parkinson's disease
- Theophylline, a medicine used to treat asthma
- Muscle relaxants
- Some pain relievers.

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

4. How do I use NORMISON?

How much to take

- The dose of NORMISON varies from patient to patient.
- Your doctor will tell you how many tablets you need to take each day. This depends on your condition and whether or not you are taking any other medicines.
- The usual starting dose is one 10 mg tablet each night.
- Elderly people over 65 years of age may need smaller doses.

When to take/use NORMISON

- Your doctor will tell you when to take NORMISON. This depends on your condition and whether or not you are taking any other medicines.
- NORMISON is usually used for short periods only (such as 2 to 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.
- Follow the instructions provided and use NORMISON until your doctor tells you to stop.

How to take NORMISON

- Swallow NORMISON with a glass of water.
- NORMISON can be taken with or without food.

If you forget to use NORMISON

NORMISON should be used regularly at the same time each day. If you forget to take NORMISON before you go to bed and you wake up late in the night or early in the morning, do not take NORMISON as you may have trouble waking in the morning.

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.

This may increase the chance of you getting an unwanted side effect.

If you are unsure about whether to take your next dose, speak to your doctor or pharmacist.

If you use too much NORMISON

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

If you take too much NORMISON you may feel drowsy, confused, tired, dizzy, have difficulty breathing, feel weak, have low blood pressure, lack mobility and coordination, be unconscious, or rarely it may be fatal.

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.

5. What should I know while using NORMISON?

Things you should do

- Take NORMISON exactly as your doctor has prescribed.
- If you have to have any blood tests, tell your doctor that you are taking NORMISON. It may affect the result of some tests.
- Visit your doctor regularly so they can check on your progress. Your doctor will check your condition to see whether you should continue to take NORMISON.
- Tell your doctor if you feel this medicine is not helping your condition.
- Keep enough NORMISON to last weekends and holidays.

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.

Remind any doctor, dentist or pharmacist you visit that you are using NORMISON.

Call your doctor straight away if you:

- feel this medicine is not helping your condition.
- become pregnant while you are taking NORMISON.

All thoughts of suicide must be taken seriously. Tell your doctor or a mental health professional immediately if you have any suicidal thoughts or other mental/mood changes

Things you should not do

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

- Do not take NORMISON for a longer time than your doctor has prescribed.
- Do not use this medicine to treat any other complaints unless your doctor tells you to.
- Do not give it to anyone else, even if they have the same condition as you.

Stopping NORMISON suddenly may cause some unwanted withdrawal effects. It is more common in patients that have received high doses over longer periods of time.

Withdrawal symptoms include insomnia, anxiety, unusual mood, panic attacks, dizziness, light sensitivity, confusion, (seeing or hearing things that are not real (hallucinations), vomiting, sweating, fits (convulsions), a feeling of loss of identity/feeling detached from yourself (depersonalisation or derealisation) and loss of short-term memory.

Your doctor may want you to gradually reduce the amount you are taking before stopping completely. This may help reduce the possibility of unwanted side effects.

Driving or using machines

Be careful before you drive or use any machines or tools until you know how NORMISON affects you.

NORMISON may cause drowsiness or dizziness in some people. Even though you take NORMISON at night, you may still be drowsy or dizzy the next day.

Make sure you know how you react to NORMISON before you drive a car, 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.

Combining NORMISON and alcohol can make you more sleepy, dizzy or light-headed or increase the risk of sleep walking and some other related sleep behaviours which may include sleep-driving, making phone calls, or preparing and eating food while asleep.

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

Looking after your medicine

- Keep your tablets in their blister pack until it is time to take them. If you take the tablets out of the blister pack they may not keep well.
- Keep your medicine in a cool dry place where the temperature stays below 30°C

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.

Getting rid of any unwanted medicine

If your doctor tells you to stop taking NORMISON or the tablets have passed their expiry date, ask your pharmacist what to do with any tablets left over.

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"> • dizziness, drowsiness, feeling tired • light-headedness or feeling faint • headache • nausea, vomiting, stomach pain, dry mouth • unpleasant dreams • slurred speech • blurred vision • tingling or numbness of the hands or feet • change in libido or sex drive. 	<p>Speak to your doctor if you have any of these less serious side effects and they worry you.</p>

Serious side effects

Serious side effects	What to do
<ul style="list-style-type: none"> • confusion, loss of memory, disorientation • behavioural or mood changes such as sudden outbursts of anger and increased excitement • signs of frequent infections such as fever, chills, sore throat or mouth ulcers • yellowing of the eyes and skin (jaundice) • dark coloured urine. <p>Go straight to the Emergency Department at your hospital if you get the below side effects:</p> <ul style="list-style-type: none"> • fainting • hallucinations • any type of skin rashes, itching or hives • swelling of the face, lips or tongue which may cause 	<p>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.</p>

difficulty in swallowing or breathing <ul style="list-style-type: none"> wheezing or shortness of breath. 	
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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 NORMISON contains

Active ingredient (main ingredient)	10 mg temazepam
Other ingredients (inactive ingredients)	lactose monohydrate microcrystalline cellulose maize starch magnesium stearate
Potential allergens	Lactose

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

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

What NORMISON looks like

NORMISON 10 mg are white, round, biconvex tablets with one side plain and the other with a stylised "S".

Available in blister packs of 25 tablets.

Australian Registration Number: AUST R 41637

Who distributes NORMISON

In Australia:
Aspen Pharma Pty Ltd
34-36 Chandos Street
St Leonards NSW 2065
(AUST R 41637)

In New Zealand:
Pharmacy Retailing (NZ) Ltd t/a
Healthcare Logistics
58 Richard Pearse Drive
Airport Oaks
Mangere, Auckland
Telephone: (09) 9185 100
Fax: (09) 9185 101

This leaflet was prepared in October 2022.