

NORMISON

temazepam

Consumer Medicine Information (CMI)

What is in this leaflet

This leaflet answers some common questions about NORMISON. It does not contain all of 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 NORMISON against the benefits they expect it will have for you.

If you have any concerns about taking this medicine, ask your doctor or pharmacist.

Keep this leaflet with the medicine.

You may need to read it again.

What NORMISON is used for

NORMISON is used to treat sleeping problems, also called insomnia. It contains the active ingredient temazepam, a benzodiazepine. It is thought to work by acting on the brain chemicals.

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.

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

Your doctor may have prescribed this medicine for another reason.

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

Before you take it

When you must not take it

Do not take NORMISON if you are allergic to:

- Temazepam or any other benzodiazepine medicines
- 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.

Do not take NORMISON if you have:

- severe and chronic lung disease or breathing difficulties
- sleep apnoea
- depression with or without anxiety problems. Temazepam can increase thoughts of death or suicide.

Do not take NORMISON if the packaging shows signs of tampering or the tablets do not look quite right.

Do not take this medicine if the expiry date (EXP) printed on the pack has passed.

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.

Before you take it

Tell your doctor if you are allergic to any other medicines, foods, dyes or preservatives.

Tell your doctor if you are pregnant or plan to become pregnant.

Like other benzodiazepine medicines, NORMISON may cause unwanted effects in the newborn baby if used during pregnancy. Your doctor will discuss the risks and benefits of taking NORMISON during pregnancy.

Tell your doctor you are breastfeeding or wish 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.

Tell 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
- any blood disorder
- glaucoma (increased pressure in the eye)
- depression, psychosis or schizophrenia
- drug or alcohol dependence or a past history of these problems.

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

Tell your doctor if you drink alcohol regularly.

Alcohol may increase the effects of NORMISON.

Tell your doctor if you plan to have surgery.

If you have not told your doctor about any of the above, tell them before you take any NORMISON.

Taking other medicines

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

Some medicines may interfere with NORMISON. 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.

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

If you are not sure whether you are taking any of these medicines, check with your doctor or pharmacist.

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

How to take it

Follow all directions given to you by your doctor and pharmacist carefully.

They may differ from the information contained in this leaflet.

How much to take

The dose of NORMISON varies from patient to patient.

The usual starting dose is one 10 mg tablet each night. Your doctor will tell you how many tablets you need to take each day and when to take them. This depends on your condition and whether or not you are taking any other medicines.

Elderly people over 65 years of age may need smaller doses.

How to take it

Swallow NORMISON with a glass of water.

NORMISON can be taken with or without food.

How long to take it

Take NORMISON only for as long as your doctor recommends.

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.

If you forget to take it

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.

Do not take a double dose to make up for the dose that 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 have trouble remembering when to take your medicine, ask your pharmacist for some hints.

If you take too much (overdose)

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

You may need urgent medical attention. If you take too much NORMISON you may feel drowsy, confused, tired, dizzy, have difficulty breathing, feel weak or become unconscious.

While you are taking it

Things you must do

Take NORMISON exactly as your doctor has prescribed.

Tell all doctors, dentists and pharmacists who are treating you that you are taking NORMISON.

If you become pregnant while you are taking NORMISON, tell your doctor immediately.

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.

If you have to have any blood tests, tell your doctor that you are taking NORMISON.

It may affect the results of some tests.

Keep enough NORMISON to last weekends and holidays.

Things you must not do

Do not drive or operate machinery 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.

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

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

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

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.

Things to be careful of

Be careful when drinking alcohol while taking NORMISON.

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.

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.

Side effects

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are using NORMISON.

Like all other medicines, it may have unwanted side effects in some people. Sometimes they are serious, most of the time they are not. You may need medical treatment if you get some of the side effects.

Do not be alarmed by this list of possible side effects.

You may not experience any of them.

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

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

- 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.

Tell your doctor immediately if you notice any of the following:

- 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.

The above list includes serious side effects which may require medical attention.

Tell your doctor immediately or go to Accident and Emergency at the nearest hospital if you notice any of the following:

- fainting
- hallucinations
- any type of skin rashes, itching or hives
- swelling of the face, lips or tongue which may cause difficulty in swallowing or breathing
- wheezing or shortness of breath.

The side effects listed above are serious and require urgent medical attention or hospitalisation.

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

Other side effects not listed above may also occur in some patients.

After taking it

Storage

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.

Do not store it or any other medicines in the bathroom or

near a sink. Do not leave it in the car or on window sills.

Heat and dampness can destroy some medicines.

Keep it where children cannot reach it.

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

Disposal

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.

Healthcare Logistics
58 Richard Pearse Drive
Airport Oaks
Mangere, Auckland

Telephone: (09) 9185 100
Fax: (09) 9185 101

Australian Registration Number:
AUST R 41637

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Product description

What it 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.

Ingredients

Each NORMISON tablet contains 10 mg temazepam, as the active ingredient.

They also contain:

- ◆ lactose monohydrate
- ◆ microcrystalline cellulose
- ◆ maize starch
- ◆ magnesium stearate

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

Sponsor

Manufactured in Australia by
Aspen Pharma Pty Ltd.

Supplied in New Zealand by:

Pharmacy Retailing (NZ) Ltd t/a