

Midazolam Te Arai

Midazolam Te Arai 2.5 mg/0.5 mL oromucosal solution

Midazolam Te Arai 5 mg/1 mL oromucosal solution

Midazolam Te Arai 7.5 mg/1.5 mL oromucosal solution

Midazolam Te Arai 10 mg/2 mL oromucosal solution

What is in this leaflet

Please read this leaflet carefully before you start using Midazolam Te Arai.

This leaflet answers some common questions about Midazolam Te Arai. 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 using Midazolam Te Arai against the benefits they expect it will have for you.

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

Keep this leaflet with the medicine. You may need to read it again.

What Midazolam Te Arai is used for

Midazolam Te Arai is an oromucosal solution, containing midazolam. Midazolam belongs to a group of medicines known as benzodiazepines. Midazolam Te Arai is used to stop a sudden, prolonged, convulsive, seizure in infants from 3 months to adults.

In infants from 3 to less than 6 months it should only be used in a hospital setting where monitoring is possible and resuscitation equipment is available.

This medicine must only be used by parents/carers where the patient has been diagnosed to have epilepsy.

Your doctor may have prescribed Midazolam Te Arai for another reason.

Ask your doctor if you have any questions about why Midazolam Te Arai has been prescribed for you.

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

Before you use Midazolam Te Arai

When you must not use it

Do not use Midazolam Te Arai if the patient has:

- An allergy to midazolam, benzodiazepines (such as diazepam) or any of the other ingredients of this medicine (listed in the Product Description section below)
- A disease of the nerves and muscles causing muscle weakness (myasthenia gravis)
- Severe difficulty breathing at rest (midazolam can make breathing difficulties worse)
- An illness causing frequent interruption of breathing during sleep (sleep apnoea syndrome)
- Severe liver problems.

If you are not sure whether you should start using Midazolam Te Arai, talk to your doctor.

Before you start to use it

Children:

Tell your doctor if the patient has:

- A kidney, liver or heart condition
- A lung condition that causes difficulty breathing on a regular basis

Adults:

Talk to your doctor if:

- You are over 60 years of age.
- You have a long-term illness (such as breathing problems or kidney, liver or heart problems).
- You are debilitated (have an illness that makes you very weak, run down and short of energy).

This medicine may cause people to forget what happened after they have been given it. Patients should be observed carefully after being given the medicine.

This medicine should be avoided in patients with a medical history of alcohol or drug abuse.

Life threatening incidents are more likely in patients with breathing difficulties or heart problems, especially when higher doses of midazolam are given.

Children younger than 3 months:

Midazolam Te Arai should not be given to children younger than 3 months since there is not enough information in this age group.

Elderly:

The elderly are more sensitive to the effects of benzodiazepines.

If you have not told your doctor about any of the above, tell them before you start using Midazolam Te Arai.

Taking other medicines

Tell your doctor if you are taking any other medicines, including medicines that you buy without a prescription from your pharmacy, supermarket or health food shop. You should also tell any health professional who is prescribing a new medication for you that you are taking Midazolam Te Arai.

Some medicines may interfere with Midazolam Te Arai.

The effects of Midazolam Te Arai may be intensified by medicines such as:

- antiepileptics, (for treating epilepsy) e.g. phenytoin
- antibiotics, e.g. erythromycin, clarithromycin
- antifungals, e.g. ketoconazole, voriconazole, fluconazole, itraconazole, posaconazole
- anti-ulcer medicines, e.g. cimetidine, ranitidine and omeprazole
- medicines used to treat blood pressure, e.g. diltiazem, verapamil
- some medicines used to treat HIV and AIDS, e.g. saquinavir, lopinavir/ritonavir combination
- narcotic analgesics (very strong pain killers), e.g. fentanyl
- medicines used to reduce fat in the blood, e.g. atorvastatin
- medicines used to treat nausea, e.g. nabilone
- hypnotics (sleep inducing medicines)
- sedative antidepressants (medicines used to treat depression that make you sleepy)
- sedatives (medicines that relax you)
- anaesthetics (for pain relief)
- antihistamines (to treat allergies).

The effects of Midazolam Te Arai may be reduced by medicines such as:

- rifampicin (used to treat tuberculosis)
- xanthines (used to treat asthma)
- St John's Wort (a herbal medicine). This should be avoided in patients taking Midazolam Te Arai.

Midazolam Te Arai may increase the effect of some muscle relaxants e.g. baclofen (causing increased drowsiness). This medicine may also stop some other medicines from working as well, e.g. levodopa (used to treat Parkinson's disease).

These medicines may be affected by Midazolam Te Arai, or may affect how well it works. You may need different amounts of your medicine, or you may need to take different medicines.

Your doctor or pharmacist has more information on medicines to be careful with or avoid while taking Midazolam Te Arai.

How to use Midazolam Te Arai

How much to take

Always give this medicine exactly as a doctor has told you. Check with a doctor or pharmacist if you are not sure.

Dosage

The doctor will prescribe the appropriate dose of Midazolam Te Arai the patient needs, generally according to the patient age. The different doses each have a different colour, which is shown on the carton, the tube and the syringe containing the medicine.

Depending on age, the patient will have received one of the following doses, in specifically colour labelled packaging:

Age range	Strength	Label colour
3 months to less than 1 year	2.5 mg	Yellow
1 year to less than 5 years	5 mg	Blue
5 years to less than 10 years	7.5 mg	Purple
10 years to adults	10 mg	Orange

The dose is the full contents of one oral syringe. Do not give more than one dose.

Toddlers aged from 3 months to less than 6 months should only be treated in a hospital setting where monitoring is possible and resuscitation equipment is available.

When to take it

If the patient is having a seizure, allow their body to move freely, do not try to restrain them. Only move them if they are in danger from, for example, deep water, fire or sharp objects.

Support the patient's head with something soft, such as a cushion or your lap.

Check that the medicine is the correct dose for the patient, according to their age.

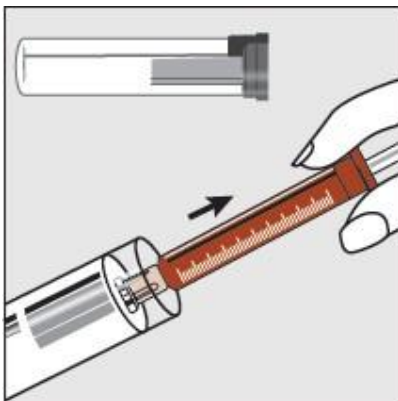
How to give it

Ask a doctor, pharmacist or nurse to show you how to take or administer this medicine. Always check with them if you are not sure.

The information on how to give this medicine is also shown on the tube label.

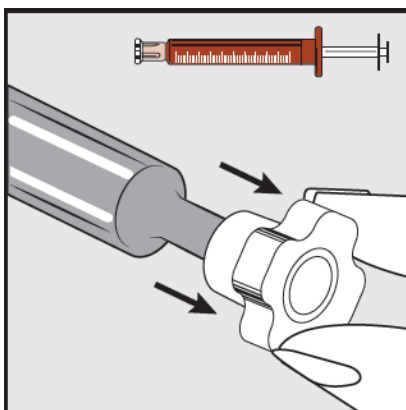
Midazolam Te Arai must not be injected. Do not attach a needle to the syringe.

Step 1



Hold the plastic tube, break the seal at one end and pull the cap off. Take the syringe out of the tube.

Step 2



Pull the transparent syringe cap off the tip of the syringe and dispose of it safely.

Step 3



Using the finger and thumb gently pinch and pull back the patient's cheek. Put the tip of the syringe into the back of the space between the inside of the cheek and the lower gum.

Step 4



Slowly press the syringe plunger until the plunger stops.

The full amount of solution should be inserted slowly into the space between the gum and the cheek (buccal cavity).

If prescribed by your doctor (for larger volumes and/or smaller patients), you can give approximately half the dose slowly into one side of the mouth, then into the other side of the patient's mouth.

When to call an ambulance

ALWAYS follow the treatment advice provided by the patient's doctor or as explained by a healthcare professional. If in any doubt, call for immediate medical help if:

- The seizure does not stop within 10 minutes
- You're unable to empty the syringe or you spill some of the contents
- The patient's breathing slows down or stops e.g. slow or shallow breathing or blue lips
- You observe signs of a heart attack which may include chest pain or pain that spreads to the neck and shoulders and down the left arm

- The patient is sick (vomits) and the seizure does not stop within 10 minutes
- You give too much Midazolam Te Arai and there are signs of overdose which include:
 - Drowsiness, tiredness, fatigue
 - Confusion or feeling disorientated
 - Absence of knee reflex or a response to a pinch
 - Breathing difficulties (slow or shallow breathing)
 - Low blood pressure (giddiness and feeling faint)
 - Coma

Keep the syringe to show to the ambulance staff or doctor.

Do not give more than the amount of medicine prescribed by a doctor for the patient.

If the patient is sick (vomits)

- Do not give the patient another dose of Midazolam Te Arai.
- If the seizure does not stop within 10 minutes, call an ambulance.

If you have any further questions on the use of this medicine, ask a doctor or pharmacist.

While you are using Midazolam Te Arai

Things you must do

If the patient who will be given this medicine is pregnant or breast-feeding, thinks she may be pregnant or is planning to have a baby, ask a doctor for advice before taking this medicine.

Giving high doses of midazolam during the last 3 months of pregnancy can cause abnormal heart beat in the unborn child. Babies born after this medicine is administered during childbirth can also have poor suckling, breathing difficulties, and poor muscle tone at birth.

Tell the doctor if the patient is breast-feeding. Even though small amounts of midazolam may pass into breast milk, it may not be necessary to stop breast-feeding. The doctor will advise if the patient should breast-feed after being given a single dose of this medicine.

If you are about to be started on any new medicine tell your doctor and pharmacist that you are taking Midazolam Te Arai.

Things you must not do

Do not give Midazolam Te Arai to anyone else, even if they have the same condition as you.

Things to be careful of

Driving and using machines

Midazolam may make the patient sleepy, forgetful or affect their concentration and co-ordination. This may affect their performance at skilled tasks such as driving, riding a bicycle, or using machines.

After receiving this medicine, the patient should not drive a vehicle, ride a bicycle or operate a machine until they have completely recovered. Please discuss with your doctor if you need further advice.

Midazolam Te Arai contains sodium

This medicine contains less than 1 mmol sodium (23 mg) per dosage unit, that is to say essentially 'sodium-free'.

Midazolam with food and drink

The patient must not drink alcohol while taking midazolam. Alcohol may increase the sedative effects of this medicine and make them very sleepy.

The patient must not drink grapefruit juice while taking midazolam. Grapefruit juice may increase the sedative effects of this medicine and make them very sleepy.

In case of overdose

If you take too much (overdose)

Immediately telephone your doctor or the National Poisons Centre (telephone 0800 POISON or 0800 764 766), or go to accident and emergency at your nearest hospital, if you think that you or anyone else may have taken too much Midazolam Te Arai.

Do this even if there are no signs of discomfort or poisoning.

Signs of overdose of Midazolam Te Arai include:

- Drowsiness, tiredness, fatigue
- Confusion or feeling disorientated
- Absence of knee reflex or a response to a pinch
- Breathing difficulties (slow or shallow breathing)
- Low blood pressure (giddiness and feeling faint)
- Coma

Side Effects

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

All medicines can have side effects. Sometimes they are serious, most of the time they are not. You may need medical treatment if you get some of the adverse effects. Ask your doctor or pharmacist to answer any questions you may have.

Serious side effects

Seek medical advice immediately or telephone for an ambulance if the patient experiences the following:

- Severe breathing difficulties e.g. slow or shallow breathing or blue lips. In very rare cases breathing might stop.
- Heart attack. Signs may include chest pain which may spread to the patient's neck and shoulders and down their left arm.
- Swelling of the face, lips, tongue or throat which makes it difficult to swallow or breathe, or a pale skin, a weak and rapid pulse, or feeling of loss of consciousness. You may be having a serious allergic reaction.

Other side effects

If the patient gets any side effects, talk to their doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet.

Common side effects (may affect up to 1 in 10 people):

- Feeling and being sick
- Sleepiness or losing consciousness

Uncommon side effects (may affect up to 1 in 100 people):

- Rash, hives (lumpy rash), itchiness

Other adverse effects not listed above may also occur in some patients. Tell your doctor if you notice any other effects.

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

After using Midazolam Te Arai

Storage

Keep this medicine out of the sight and reach of children.

Do not give this medicine after the expiry date which is stated on the carton, tube and oral syringe labels after EXP. The expiry date refers to the last day of that month.

Keep the oral syringe in the protective plastic tube.
Do not freeze.
Do not store above 30°C.

Do not use this medicine if the packaging has been opened or damaged.

Disposal

Do not throw away any medicines or oral syringes via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help to protect the environment.

Product description

What it looks like

Midazolam Te Arai 2.5 mg/0.5 mL - yellow labelled packaging
Midazolam Te Arai 5 mg/1 mL - blue labelled packaging
Midazolam Te Arai 7.5 mg/1.5 mL - purple labelled packaging
Midazolam Te Arai 10 mg/2 mL - orange labelled packaging

Midazolam Te Arai oromucosal solution is a clear liquid.

It is supplied in an amber coloured pre-filled needle-free, oral syringe with a plunger and end cap. Each oral syringe is individually packed in a protective plastic tube.

Midazolam Te Arai is available in cartons containing 1 pre-filled oral syringe (of the same dose).

Ingredients

Active ingredient:

- 2.5 mg/0.5 mL - Each pre-filled oral syringe contains midazolam hydrochloride equivalent to 2.5 mg midazolam in 0.5 ml solution.
- 5 mg/1 mL - Each pre-filled oral syringe contains midazolam hydrochloride equivalent to 5 mg midazolam in 1 ml solution.
- 7.5 mg/1.5 mL - Each pre-filled oral syringe contains midazolam hydrochloride equivalent to 7.5 mg midazolam in 1.5 ml solution.
- 10 mg/2 mL - Each pre-filled oral syringe contains midazolam hydrochloride equivalent to 10 mg in 2 ml solution.

Inactive ingredients:

The other ingredients are sodium chloride, purified water, hydrochloric acid and sodium hydroxide (for pH adjustment).

Sponsor Details

Midazolam Te Arai is supplied in New Zealand by:

Te Arai BioFarma Limited

PO Box 46205
Herne Bay
Auckland 1147
NEW ZEALAND

0800 832 724

Date of Preparation

This leaflet was prepared on 9 April 2026.