Package leaflet: Information for the user

Midazolam Medical Valley 2.5 mg oromucosal solution
Midazolam Medical Valley 5 mg oromucosal solution
Midazolam Medical Valley 7.5 mg oromucosal solution
Midazolam Medical Valley 10 mg oromucosal solution

midazolam

Read all of this leaflet carefully, before you start giving this medicine because it contains important information for you.
- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as those of the patient for whom this medicine has been prescribed.
- If you see any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet:

1. What <invented name> is and what it is used for

<invented name> oromucosal solution contains a medicine called midazolam. Midazolam belongs to a group of medicines known as benzodiazepines.

<invented name> 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.

2. What you need to know before you give <invented name> Do not give <invented name> if the patient has:
- An allergy to midazolam, benzodiazepines (such as diazepam) or any of the other ingredients of this medicine (listed in section 6)
- A disease of the nerves and muscles causing muscle weakness (myasthenia gravis)
- Severe difficulty breathing at rest (<invented name> can make breathing difficulties worse)
- An illness causing frequent interruption of breathing during sleep (sleep apnoea syndrome)
- Severe liver problems.

Warnings and precautions

Children:
Talk to your doctor or pharmacist before giving <invented name> 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 or pharmacist before you are given <invented name> 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 feel 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 <invented name> are given.

Children younger than 3 months:
<invented name> 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 are not sure if any of the above applies to the patient, talk to a doctor or pharmacist before giving this medicine.

Other medicines and <invented name>
Tell your doctor or pharmacist if the patient is taking, or has recently taken, or might take any other medicines. If you have any doubt about whether any medicine the patient is taking may affect the use of <invented name>, please speak to your doctor or pharmacist.

This is extremely important, as using more than one medicine at the same time can strengthen or weaken the effect of the medicines involved.

The effects of <invented name> 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, pozaconazole
- 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 <invented name> 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 <invented

name>.

<invented name> 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).

Talk to your doctor or pharmacist about medicines the patient should avoid whilst taking <invented name>.

<invented name> with food and drink
The patient must not drink alcohol while taking <invented name>. Alcohol may increase the sedative effects of this medicine and make them very sleepy.

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

Pregnancy
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 <invented name> 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.

Breast-feeding
Tell the doctor if the patient is breast-feeding. Even though small amounts of <invented name> 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 this medicine.

Driving and using machines
<invented name> 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.

<invented name> contains sodium
This medicine contains less than 1 mmol sodium (23 mg) per oral syringe, that is to say essentially 'sodium-free'.

3. How to give <invented name>

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 <invented name> 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.

Preparing to give this medicine

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.

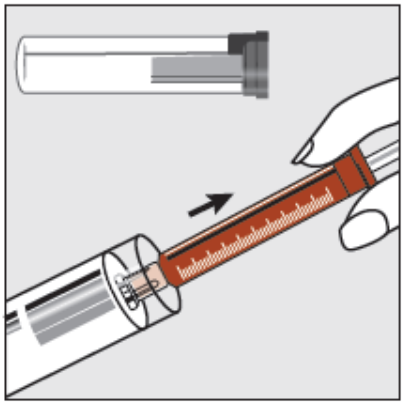
Support the patient's head with something soft, such as a cushion or your lap.

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

How to give this medicine
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.

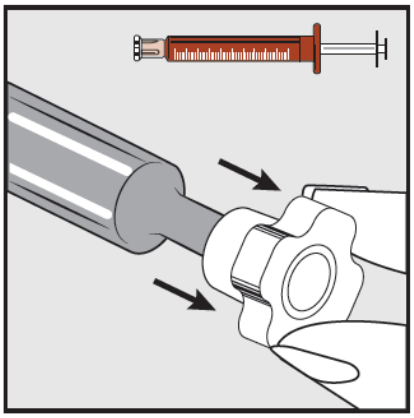
The information on how to give this medicine is also shown on the tube label.
<invented name> must not be injected. Do not attach a needle to the syringe

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 <invented name> 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 <invented name>.
- 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.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

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

Very rare side effects (may affect up to 1 in 10 000 people):
- Agitation, restlessness, hostility, rage or aggression, excitement, confusion, euphoria (an excessive feeling of happiness or excitement), or hallucinations (seeing and possibly hearing things that are not really there)
- Muscle spasms and muscle tremors (shaking of your muscles that you cannot control)
- Reduced alertness
- Headache
- Dizziness
- Difficulty co-ordinating muscles

- Fits (convulsions)
- Temporary memory loss. How long this lasts depends on how much <invented name> was given.
- Low blood pressure, slow heart rate, or redness of the face and neck (flushing)
- Laryngospasm (tightening of the vocal cords causing difficult and noisy breathing)
- Constipation
- Dry mouth
- Tiredness
- Hiccups

Reporting of side effects
If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the national reporting system listed in Appendix V. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store <invented name>

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 store above 30ºC

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

Disposal of oral syringes
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.

6. Contents of the pack and other information

What <invented name> contains
- The active substance is midazolam
- 2.5 mg - Each pre-filled oral syringe contains midazolam hydrochloride equivalent to 2.5 midazolam in 0.5 ml solution.
- 5 mg - Each pre-filled oral syringe contains midazolam hydrochloride equivalent to 5 mg midazolam in 1 ml solution.
- 7.5 mg - Each pre-filled oral syringe contains midazolam hydrochloride equivalent to 7.5 mg midazolam in 1.5 ml solution.
- 10 mg - Each pre-filled oral syringe contains midazolam hydrochloride equivalent to 10 mg in 2 ml solution.

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

What<invented name> looks like and contents of the pack
2.5 mg - yellow labelled packaging
5 mg - blue labelled packaging
7.5 mg - purple labelled packaging
10 mg - orange labelled packaging

<invented name> 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.

<invented name> is available in cartons containing 2 or 4 pre-filled oral syringes (of the same dose).

Not all pack sizes may be marketed.

Marketing Authorisation Holder

[To be completed nationally].

Manufacturer
Laboratorios Liconsa S.A.
Av. de Miralcampo, 7
19200 Azuqueca de Henares
Guadalajara
SPAIN

This medicinal product is authorised in the Member States of the EEA under the following names:

- SE: Midazolam Medical Valley 2.5 mg, 5 mg, 7.5 mg, 10 mg munhålelösning.
- FI: Midazolam Medical Valley 2.5 mg, 5 mg, 7.5 mg, 10 mg liuos suuonteloon.
- DE: Midazolam Desitin 2,5 mg, 5 mg, 7.5 mg, 10 mg Lösung zur Anwendung in der Mundhöhle.
- NO: Midazolam Medical Valley 2.5 mg, 5 mg, 7.5 mg, 10 mg munnvann, oppløsning.
- NL: Midazolam Xiromed 2.5 mg, 5 mg, 7.5 mg, 10 mg oplossing voor oromucosaal gebruik.
- DK: Midazolam Medical Valley 2.5 mg, 5 mg, 7.5 mg, 10 mg mundhulevæske, opløsning.
- IS: Midazolam Medical Valley 2.5 mg, 5 mg, 7.5 mg, 10 mg munnholslausn.
- FR: Midazolam Exeltis 2.5 mg, 5 mg, 7.5 mg, 10 mg solution buccale.
- IE: Midazolam Rowa 2.5 mg, 5 mg, 7.5 mg, 10 mg oromucosal solution.
- RO: Midazolam Desitin 2.5 mg, 5 mg, 7.5 mg, 10 mg soluție bucofaringiană
- ES: Oroxelam 2.5 mg, 5 mg, 7.5 mg, 10 mg solución bucal.
- PL: Soloxelam.
- IT: Oroxelam.

This leaflet was last revised in 26 September 2025

Other sources of information

Detailed information on this medicine is available on the website of {name of Member State Agency (link)}