**Package leaflet: Information for the user**

# Miprosed 5mg/ml Oral Solution

midazolam

**Read all of this leaflet carefully before you or your child is given 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, nurse or pharmacist.
- If you or your child experiences any side effects, talk to your doctor, nurse or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

The name of your medicine is Miprosed 5mg/ml Oral Solution but it will be referred to as 'Miprosed' throughout this leaflet.

**What is in this leaflet:**



## 1. What Miprosed is and what it is used for

Miprosed contains an active substance midazolam. Midazolam is a member of a group of medicines called benzodiazepines which can help to relieve anxiety. Midazolam is used for sedation and anxiolysis prior to diagnostic, surgical, therapeutic or endoscopic procedures and as a premedication before being induced for general anaesthesia in children aged between 6 months and 14 years.

## 2. What you need to know before you or your child use Miprosed

**Do not give Miprosed if the patient has:**

- an allergy (hypersensitivity) to midazolam, to any other benzodiazepines (such as diazepam) or to any of the other ingredients of this medicine (listed in section 6)
- severe liver disease
- a disorder of the nerves or muscles that have severe muscle weakness (myasthenia gravis)
- severe breathing problems
- a condition that temporarily stops breathing during sleep (sleep apnea syndrome)

Do not use this medicine if any of the above apply to the patient. If you are not sure, talk to your doctor or pharmacist before using Miprosed.

**Warnings and precautions**

Miprosed should be administered only by experienced physicians in a setting fully equipped for the monitoring and support of respiratory and cardiovascular function and by persons specifically trained in the recognition and management of expected adverse events including respiratory and cardiac resuscitation.

Talk to the doctor, nurse or pharmacist before Miprosed is given if the person who is going to receive it:

- has a mild, moderate or long-term illness (such as breathing, kidney, liver or heart problems)
- has poor overall health
- abuses or has in the past abused drugs or alcohol
- is younger than 6 months.

**Other medicines and Miprosed**

Tell the doctor or pharmacist if the patient who is going to receive Miprosed is using, has recently used or might use any other medicines. This includes medicines obtained without a prescription, including herbal medicines. This is because Miprosed can affect the way some other medicines work. Also, some medicines can affect the way Miprosed works.

In particular, tell the doctor or nurse or pharmacist if the patient who is going to receive Miprosed is taking any of the following:

- narcotic analgesics (e.g. fentanyl)
- herbal medicines (e.g. St. Johns Wort)
- medicines for epilepsy (e.g. carbamazepine, phenytoin)
- medicines for high blood pressure and angina (e.g. diltiazem and verapamil)
- medicines for indigestion, acid reflux or ulcer treatment (e.g. cimetidine, ranitidine and omeprazole)
- medicines for asthma (e.g. theophylline, aminophylline and other xanthine's)
- medicines used to treat Parkinson's disease (e.g. levodopa)
- muscle relaxants (e.g. baclofen)
- medicines used for nausea and/or vomiting (e.g. nabilone and aprepitant)
- medicines for fungal infections (e.g. ketoconazole, voriconazole, fluconazole, itraconazole and posaconazole)
- certain antibiotics (rifampicin, macrolide antibiotics e.g. erythromycin and clarithromycin)
- medicines used to treat HIV called protease inhibitors (e.g. saquinavir)
- medicines used for high cholesterol (e.g. atorvastatin)
- medicines used to treat depression that make your child sleepy (sedative antidepressants)
- other medicines for the treatment of depression (antidepressant, e.g. fluvoxamine)
- medicines used for the treatment of involuntary urine loss (e.g. propiverine).

Using Miprosed together with other sedative/hypnotic medicines may cause increased sleepiness or breathing problems. Examples of sedative/hypnotic medicines include medicines used to treat mood or mental disorders, barbiturates, propofol, ketamine, etomidate, medicines used to treat allergies and some classes of medicine used to treat high blood pressure.

Concomitant use of Miprosed and opioids (strong pain killers, medicines for substitution therapy and some cough medicines) increases the risk of drowsiness, difficulties in breathing (respiratory depression), coma and may be life-threatening. Because of this, concomitant use should only be considered when other treatment options are not possible.

However, if the doctor does prescribe Miprosed together with opioids, the dose and duration of concomitant treatment should be limited by the doctor.

Please tell the doctor about all opioid medicines patient is taking and follow the doctor's dose recommendation closely. It could be helpful to inform the patient's friends or relatives to be aware of the signs and symptoms stated above. Contact the doctor when patient is experiencing such symptoms.

Do not use this medicine if any of the above apply to the patient. If you are not sure, talk to the doctor, nurse or pharmacist before using Miprosed.

**Miprosed with food, drink and alcohol**

Grapefruit juice and drinks containing caffeine should be avoided as they can affect the way that Miprosed works. The patient should not drink alcohol while taking Miprosed. Alcohol may increase the sedative effects of Miprosed and make the patient sleepier.

**Pregnancy, breast-feeding and fertility**

- If your child is pregnant, thinks she might be pregnant or is planning to have a baby, then contact your child's doctor before your child take this medicine
- If your child is breastfeeding, she should be told not to breastfeed in the first 24 hours after taking Miprosed because midazolam passes into breast milk in small amount.

**Driving and using machines**

Miprosed may make the patient feel sleepy, forgetful, affect the level of concentration and reduce muscle function. This may negatively affect their performance at skilled tasks such as driving a vehicle or operating machinery.



TURN OVER

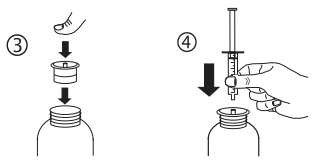
**The following information is intended for healthcare professionals only:**

- For oral and single use only.
- Use syringes (in ml) as provided.
- Discard bottle and syringes immediately after use.
- The solution must be visually checked before use. Do not use this medicine for visible signs of damage to the solution (e.g. particles are present) or packaging.
- Grapefruit juice and drinks containing caffeine should be avoided as they can affect the way that Miprosed works.
- Miprosed is incompatible with cranberry juice.

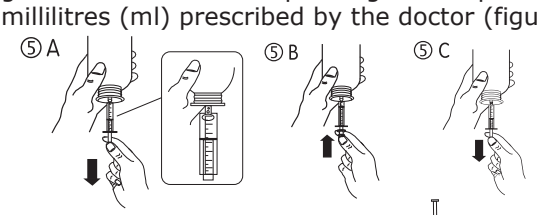
Instructions for the use of syringe:

a) Open the bottle: press the cap and turn it anticlockwise (figure 1). Separate the adaptor from the syringe (figure 2).

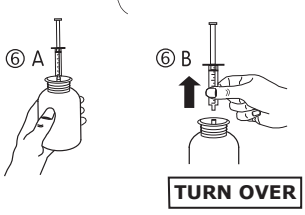

b) Insert the adaptor into the bottle neck (figure 3). Ensure it is properly fixed. Take the syringe and put it in the adaptor opening (figure 4).




c) Turn the bottle upside down. Fill the syringe with a small amount of solution by pulling the piston down (figure 5A), then push the piston upwards in order to remove any possible bubble (figure 5B). Pull the piston down to the graduation mark corresponding to the quantity in millilitres (ml) prescribed by the doctor (figure 5C).




d) Turn the bottle the right way up (figure 6A). Remove the syringe from the adaptor (figure 6B).






TURN OVER

After receiving this medicine, the patient should not drive or operate machinery until they have fully recovered.

**Miprosed contains:**

This medicine contains less than 1 mmol sodium (23 mg) in each ml of solution, that is to say essentially 'sodium-free'.

## 3 How to take Miprosed

**Instructions for use**
This medicine must be taken by mouth.
This medicine will be given to your child by a healthcare provider. It is administered in an environment with the right equipment for monitoring your child and treating possible side effects.
This medicine cannot be taken independently.
Your child should be accompanied by an adult upon discharge and leave the treatment room only after receiving authorisation from the doctor.

**If you give more Miprosed than you should**
If anyone has taken an overdose of Miprosed (that is more than the doctor has prescribed), seek medical help immediately. If a patient is accidently given or takes too much Miprosed, then he/she may feel drowsy, confused, lethargic and in more serious cases this may involve lack of voluntary muscle movement, low muscle tone, low blood pressure, breathing difficulties. Taking more Miprosed than you should may also rarely cause coma and very rarely cause death.

If you have any further questions, on the use of Miprosed, ask the doctor, nurse or pharmacist.

## 4 Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them. These are usually not serious and do not last long.

Seek medical advice immediately if the patient experiences the following:

- Severe breathing difficulties e.g. slow or shallow breathing or blue lips. In very rare cases breathing may stop.
- Heart attack. Signs may include chest pain which may spread to the patient's neck and shoulders and down their left arm.
- Hypersensitivity reactions and angioedema may occur in susceptible individuals
- Chest pain as a sign of a serious allergic reaction called Kounis syndrome has been observed.

If a patient experiences any of the following side effects, tell the doctor immediately.

**Common side effects** (may affect up to 1 in 10 people):
- Agitation
- Drowsiness
- Effect of treatment opposite than expected.

**Uncommon side effects** (may affect up to 1 in 100 people):
- Double vision
- Feeling or being sick
- Breathlessness
- Loss of control of bodily movements
- Impaired balance
- Light headedness
- Headache
- Lip biting
- Excessive/prolonged sedation
- Crying
- Change in walking pattern
- Hiccups
- Lung disease

**Rare side effects** (may affect up to 1 in 1000 people):
- Impairment of language
- Anger
- Seeing visions
- Changes in your mood
- Feeling angry or aggressive
- Screaming
- Feeling frustration
- Reduction in balance of oxygen in your blood
- Reduction in your blood pressure.

**Reporting of side effects**
If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via Yellow Card Scheme Website: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store. By reporting side effects, you can help provide more information on the safety of this medicine.

## 5. How to store Miprosed

- Keep this medicine out of the sight and reach of children.
- Do not use this medicine after the expiry date which is stated on the carton and bottle label after EXP. The expiry date refers to the last day of that month.
- This medicinal product does not require any special storage conditions.
- Do not refrigerate or freeze.
- Do not use this medicine if the solution is not clear (e.g. particles are present) or shows any signs of deterioration. Seek the advice of your pharmacist.
- Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

## 6. Contents of the pack and other information

**What Miprosed contains**
The active substance is midazolam.

Each ml of oral solution contains 5mg midazolam.

The other ingredients are sucralose, glycerol (E422), hydrochloric acid, dilute, orange flavour (contains propylene glycol (E1520)), sodium hydroxide (for pH adjustment) and purified water.

**What Miprosed looks like and contents of the pack**
Miprosed is a clear colourless to pale yellow coloured oral solution. It is supplied in a carton containing one 15ml amber glass bottle with 7.5ml oral solution with a tamper evident, child resistant, white plastic cap with polypropylene inner, polyethylene outer and an expanded polyethylene (EPE) liner. The pack also contains a 1ml oral syringe with 0.01ml graduations and a 5ml oral syringe with 0.1ml graduations together with a syringe adaptor.

**Marketing Authorisation Holder and Manufacturer:**
SyriMed,
Unit 4, Bradfield Road,
Ruislip, Middlesex,
HA4 0NU, UK

**POM**

**If this leaflet is hard to see or read, please call +44 (0) 208 515 3700 for help.**

**This medicinal product is authorised in the Member States of the EEA under the following names:**
**NL:** Miprosed 5mg/ml Drank
**DK:** Miprosed
**MT:** Miprosed 5mg/ml Oral Solution

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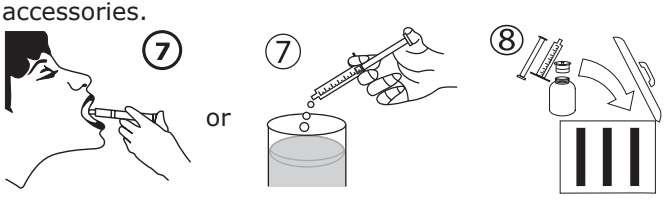
e) The syringe should be held in the mouth of the patient, and the contents of the syringe should then be emptied into the side of the mouth and swallowed. Alternatively, the contents of the syringe may be mixed with apple juice or diluted blackcurrant cordial in a glass and the whole contents of the glass should be drank (figure 7). Dispose of the bottle, the oral syringe, the syringe adaptor and any unused contents in a suitable container (figure 8) after use in accordance with local regulations for controlled substances and pharmaceutical accessories.




**Dosage**
The dosage must be adjusted to the patient's body weight. Children over 6 months of age must take a single dose of Midazolam of 0.25 to 0.5mg/kg. The maximum dose is 20mg midazolam, even for children who weigh more than 80kg (0.25mg/kg) or 40kg (0.5mg/kg).

In obese children, the dose should be administered up to a maximum of 20 mg according to actual body weight.

Midazolam must be given an average of 30 minutes prior to surgery or anesthesia.

Midazolam is not recommended for newborns (premature and mature) and babies younger than 6 months.

In the event of overdose, vomiting should be induced (as soon as possible and at least within one hour after the oral administration of midazolam) if the patient is conscious. If the patient is unconscious, a gastric lavage should be performed, protecting the airways. If the gastric lavage is not effective, activated charcoal must be administered every reduce absorption.

Flumazenil, a benzodiazepine antagonist, is indicated in the case of severe intoxication associated with respiratory depression or a coma. This treatment may only be administered under close supervision in accordance with local guidelines.