PATIENT INFORMATION LEAFLET FOR

MIRANOST

SCHEDULING STATUS:

S5

MIRANOST (5 mg/0,1 mL nasal spray)

Midazolam

Read all of this leaflet carefully before you start using MIRANOST

- Keep this leaflet. You may need to read it again.
- If you have any further questions, please ask your doctor, pharmacist, nurse or other health care provider.
- MIRANOST has been prescribed for you personally and you should not share your medicine with other people. It may harm them, even if their symptoms are the same as yours.

WARNING: RISKS FROM USING MIRANOST WITH OTHER OPIOIDS

MIRANOST is a benzodiazepine medicine. Taking benzodiazepines with opioid medicines, alcohol, or other central nervous system depressants (including street drugs) can cause severe drowsiness, breathing problems (respiratory depression), coma, and death.

What is in this leaflet

1. What MIRANOST is and what it is used for
2. What you need to know before you use MIRANOST

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3. How to use MIRANOST
4. Possible side effects
5. How to store MIRANOST
6. Contents of the pack and other information.

1. What MIRANOST is and what it is used for

MIRANOST is a benzodiazepine medicine. It belongs to a class of medicine known as anticonvulsants, including anti-epileptics.

MIRANOST is used for the short-term treatment of seizure clusters (also known as “acute repetitive seizures”) in patients 12 years of age and older.

2. What you need to know before you use MIRANOST

Do not use MIRANOST if you:

- are hypersensitive (allergic) to midazolam or any of the other ingredients of MIRANOST (listed in **section 6**).
- suffer from acute narrow-angle glaucoma (eye condition that occurs when the pressure in the eye rises quickly).

Warnings and precautions

Before you use MIRANOST, tell your healthcare provider about all your medical conditions, including any medication you are currently taking.

Take special care with MIRANOST:

- if you have a history of depression, mood problems or suicidal thoughts or behaviour.

- if you have asthma, emphysema, bronchitis, chronic obstructive pulmonary disease, or other breathing problems.
- if you are over the age of 65 years.
- if you have kidney problems.
- if you have heart failure.
- if you have a history of medicine or alcohol abuse.

MIRANOST is a benzodiazepine medicine. Taking benzodiazepines with opioid medicines, alcohol, or other central nervous system depressants (including street drugs) can cause severe drowsiness, breathing problems (respiratory depression), coma, and death.

MIRANOST may cause serious breathing problems and excessive sleepiness (sedation). Get emergency medical help right away if any of the following occur:

- unusually shallow or slowed breathing.
- stop breathing, which may lead to your heart stopping.
- unusually excessive sleepiness.

Serious side effects may occur, such as respiratory depression (slow, shallow breathing), blockage of the airway, reduced oxygen in the blood, stoppage of breathing in sleep, respiratory arrest (stop breathing) and/or cardiac arrest (sudden loss of heart function) which can result in death or permanent brain dysfunction. Decreased blood pressure, may also occur. The risk of slow, shallow breathing, blockage of the airway and stoppage of breathing in sleep is greater in elderly patients and those with chronic disease states or lung disorders.

Do not use MIRANOST with other medicines that slow your neurological function (called central nervous system depressants), such as alcohol, opiates, or barbiturates, unless directed by your doctor. Using these substances with MIRANOST may lead to shallow breathing, blockage of the airway, reduced oxygen in the blood or stoppage of breathing during sleep and may contribute to a prolonged medicine effect.

Talk to your doctor if you are taking ketoconazole, itraconazole, or clarithromycin (called strong CYP3A4 enzyme inhibitors), as it may lead to prolonged sedation with MIRANOST.

MIRANOST may cause suicidal thoughts or actions. Call a healthcare provider right away if you have any of these symptoms, especially if they are new, or getting worse:

- thoughts about suicide or dying.
- feeling agitated or restless.
- acting aggressive, being angry, or violent.
- attempts to commit suicide.
- panic attacks.
- acting on dangerous impulses.
- new or worsening depression.
- trouble sleeping (insomnia).
- an extreme increase in activity and talking (mania).
- new or worsening anxiety.
- new or worsening irritability.
- other unusual changes in behaviour or mood.

MIRANOST may impair your memory for several hours following a dose. It is recommended that you do not operate hazardous machinery or drive a motor vehicle until the effects of the medicine, such as drowsiness have subsided and as your medical condition permits. Particular care should be taken with children.

Tell your doctor if you have open-angle glaucoma (raised pressure in the eye), as you may require special precautions before using MIRANOST (see **"Do not use MIRANOST if you**").

Report to your doctor if you experience any of the following while using MIRANOST:

- agitation.
- involuntary movements.
- hyperactivity.
- combativeness.

Always use MIRANOST as directed by your doctor. Inappropriate use of MIRANOST may lead to formation of dependence and medicine abuse, while suddenly stopping your treatment may lead to withdrawal symptoms (such as convulsions, hallucinations, shakiness, stomach and muscle cramps, vomiting, and sweating). Report to your doctor if you are experiencing any of the above.

MIRANOST is not recommended for chronic, daily use as an anticonvulsant because of the potential for development of tolerance to midazolam.
Chronic daily use may increase the frequency and/or severity of tonic clonic seizures. Always use MIRANOST as directed by your doctor.

Children and adolescents

Safety and effectiveness in children below the age of 12 years have not been established.

Other medicines and MIRANOST

Always tell your healthcare professional if you are taking any other medicine. (This includes complementary or traditional medicines.)

Tell your doctor if you are taking any of the following, as you may require special precautions:

- erythromycin.
- diltiazem.
- verapamil.
- ketoconazole.
- itraconazole.
- clarithromycin.
- opioids such as, morphine, hydrocodone, oxymorphone, codeine, fentanyl.
- barbiturates, such as phenobarbitone.
- alcohol.
- benzodiazepines, anxiolytics or tranquilizers, such as alprazolam, diazepam or clonazepam.
- sedatives/hypnotics, such as zolpidem, or zaleplon.
- muscle relaxants, such as orphenadrine or baclofen.
- general anaesthetics.
- antipsychotics, such as aripiprazole, clozapine or chlorpromazine.

MIRANOST with alcohol

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Do not consume alcohol while using MIRANOST. It may increase your risk of difficult breathing, blocked airways, and decrease oxygen in your bloodstream. It may prolong the effects of MIRANOST.

Pregnancy, breastfeeding and fertility

If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist or other health care provider for advice before using MIRANOST.

Pregnancy

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

MIRANOST may harm your unborn baby.

Babies born to mothers receiving benzodiazepine medicines (including MIRANOST) late in pregnancy may be at risk of having breathing problems, feeding problems, dangerously low body temperature, and withdrawal symptoms.

Benzodiazepines, such as MIRANOST can increase the chance of having a miscarriage or losing the pregnancy early.

If you become pregnant while using MIRANOST, talk to your healthcare provider.

Breastfeeding

Tell your doctor if you are breastfeeding or plan to breastfeed. MIRANOST passes into your breast milk and may harm your baby.

Driving and using machinery

MIRANOST may affect mental and/or physical abilities to perform or execute tasks or activities requiring mental alertness, judgement and/or sound coordination, e.g. driving, riding, flying, sailing, operating machines/equipment.

MIRANOST may impair your memory for several hours or make you drowsy following a dose. It is recommended that you do not operate hazardous machinery, drive a motor vehicle or do other activities that require mental alertness until the effects of the medicine, such as drowsiness have subsided and as your medical condition permits.

It is not always possible to predict to what extent MIRANOST may interfere with the daily activities of a patient. Patients should ensure that they do not engage in the above activities until they are aware of the measure to which MIRANOST affects them.

MIRANOST contains alcohol (ethanol)

This medicine contains 7,60 mg alcohol (ethanol) in each single dose unit which is equivalent to 7,60 mg/0,1 mL (7,60 % *w/v*).

It may cause burning sensation on damaged skin.

3. How to use MIRANOST

Do not share medicines prescribed for you with any other person.

Always use MIRANOST exactly as your doctor or pharmacist has told you. You should check with your doctor or pharmacist if you are unsure.

Your doctor will tell you how long your treatment with MIRANOST will last.

If you have the impression that the effect of MIRANOST is too strong or too weak, tell your doctor or pharmacist.

Administer MIRANOST by the nasal route only.

Use MIRANOST exactly as your healthcare provider tells you and follow the **"Instructions for use"** below.

Initial dose: Administer one single-dose spray (5 mg dose) into one nostril.

Second dose (if needed): If the seizure cluster is continuing **10 minutes** after the first dose of MIRANOST, a second single-dose spray (5 mg dose) of MIRANOST **may be used if you have been told to do so by your healthcare provider**.

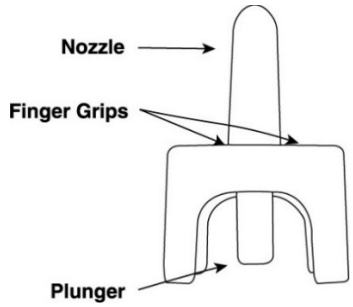
Do not give a second dose if the patient has trouble breathing or if there is excessive sedation that is uncharacteristic of the patient during a seizure cluster episode.

Do not use more than 2 doses of MIRANOST to treat a single episode. It is recommended that MIRANOST be used to treat no more than one episode every three days and no more than 5 episodes per month.

Instructions for use

You and your family members or caregivers should read these "Instructions for use" before you start using MIRANOST and each time you get a repeat prescription. There may be new information. This information does not take the place of talking to your healthcare provider about your medical condition or treatment. If you and your family members or caregivers have any questions about MIRANOST, ask your healthcare provider or pharmacist.

Important: **MIRANOST is for use in the nose only**.



- **There is only 1 dose of MIRANOST in the nasal spray unit**.
- **Do not** try to test or prime the nasal spray unit before use. You will lose the dose.
- **Do not** open the blister packaging until ready to use.
- **Do not** use if the nasal spray unit appears damaged.
- **Do not** use past the expiration date printed on the blister packaging.
- Throw away (dispose of) the nasal spray unit after use.

How to use MIRANOST:

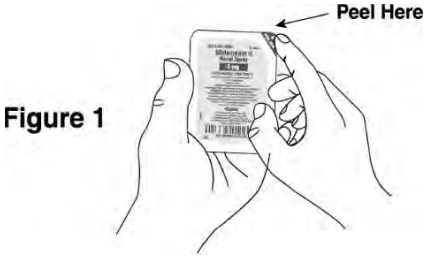


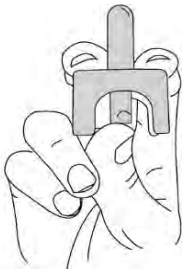
Figure 1

Step 1: Peel open the blister packaging

- When ready to use, open the blister packaging.
- Hold blister packaging in the palm of your hand.
- On the foil backing, find the "**Peel Here**" tab and pull down (see **Figure 1**).
- Remove the nasal spray unit carefully.

Step 2: Hold the nasal spray unit

Figure 2



- Hold the nasal spray unit with your thumb on the plunger and your middle and index fingers on each side of the nozzle (see **Figure 2**).
- **Do not press the plunger yet. If you press the plunger now you will lose the dose.**

Step 3: Place the tip into 1 nostril

Figure 3



- Place the tip of the nozzle into 1 nostril until your fingers on either side of the nozzle touches the bottom of the nose (see **Figure 3**).

Step 4: Press the plunger

Figure 4



- Press the plunger firmly to deliver the dose of MIRANOST (see **Figure 4**).
- Make sure to firmly press the plunger using 1 motion.

The patient does not need to breathe deeply when you give them the medicine.

What to do after the MIRANOST nasal spray has been used:

Remove the nozzle from the nostril after giving the dose.

Note: The plunger will remain inside the nasal spray unit after the dose is given.

Throw away (dispose of) the nasal spray unit and blister packaging in the trash.

What to do if a second dose is needed:

Important: If the seizure cluster is continuing **10 minutes** after the first dose of MIRANOST, a second dose of MIRANOST **may be used if you have been told to do so by your healthcare provider**.

If you need to give a second dose of MIRANOST, follow the instructions in this **"Instructions for use"** using a new nasal spray unit **in the other nostril**. (Repeat Step 1 through Step 4.)

Call for help if any of the following happens:

- Seizure or seizures continue after giving MIRANOST to the person as instructed by the healthcare provider.
- Seizure behaviour in the person is different from other episodes.
- You are alarmed by the number or severity of the seizure or seizures in the person.
- You are alarmed by the colour or breathing of the person.

If you use more MIRANOST than you should

In the event of overdosage, consult your pharmacist or doctor. If neither is available, contact the nearest hospital or poison control centre.

You may experience sedation, somnolence (excessive sleepiness), confusion, impaired coordination, diminished reflexes, coma, and untoward effects on vital signs.

If you forget to use MIRANOST

Do not use a double dose to make up for forgotten individual doses.

If you stop using MIRANOST

Always use MIRANOST as directed by your doctor. Do not stop treatment early or suddenly, since you may experience withdrawal symptoms, such as convulsions, hallucinations, tremors (shakiness), stomach and muscle cramps, vomiting, and sweating.

4. Possible side effects

MIRANOST can have side effects.

Not all side effects reported for MIRANOST are included in this leaflet. Should your general health worsen or if you experience any untoward effects while using MIRANOST, please consult your doctor, pharmacist or other healthcare professional for advice.

If any of the following happens, stop using MIRANOST and tell your doctor immediately or go to the casualty department at your nearest hospital:

- swelling of the hands, feet, ankles, face, lips, mouth, or throat, which may cause difficulty in swallowing or breathing,
- rash or itching,
- fainting.

These are all very serious side effects. If you have them, you may have had a serious allergic reaction to MIRANOST. You may need urgent medical attention or hospitalisation.

Tell your doctor immediately or go to the casualty department at your nearest hospital if you notice any of the following:

- thoughts about suicide or suicidal behaviour, worsening depression and/or any unusual changes in mood or behaviour.
- excessive sleepiness (sedation), respiratory depression (slow, shallow breathing), or coma.
- airway obstruction (blockage of the airway).
- oxygen desaturation (percentage of oxygen in blood is lower).
- apnoea (stoppage of breathing during sleep).
- respiratory arrest (stoppage of breathing).

- cardiac arrest (stop in heart function).
- central nervous system depression (poor concentration, confusion, dizziness, dry mouth).

These are all serious side effects. You may need urgent medical attention.

Tell your doctor if you notice any of the following:

Frequent side effects:

- sleepiness.
- headache.
- slurred speech (dysarthria).
- increased tearing of the eyes.
- nasal discomfort.
- throat irritation.
- runny nose (rhinorrhoea).
- abnormal taste.

Side effects with unknown frequency:

- loss of memory for several hours following an administered dose.
- agitation.
- involuntary movements.
- hyperactivity.
- combativeness.
- increase in eye pressure in patients with glaucoma.
- low blood pressure.

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

Reporting of side effects

If you get side effects, talk to your doctor, pharmacist or nurse. You can also report side effects to SAHPRA via the Med Safety APP (Medsafety X SAHPRA) and eReporting platform (who-umc.org) found on SAHPRA website or to Cipla Medpro (Pty) Ltd. by e-mail: drugsafetysa@cipla.com or telephone: 080 222 6662 (toll free). By reporting side effects, you can help provide more information on the safety of MIRANOST.

5. How to store MIRANOST

Store at or below 25 °C.

Store in the original container.

Store all medicines out of reach of children.

Return all unused medicine to your pharmacist.

Do not dispose of unused medicine in drains or sewerage systems (e.g., toilets).

6. Contents of the pack and other information

What MIRANOST contains

The active substance is midazolam. Each single-dose nasal spray unit contains midazolam 5 mg/0,1 mL.

The other ingredients are ethanol (alcohol) 7,60 % *w/v*, methoxy polyethylene glycol 350 (polyethylene glycol monomethyl ether 350), polyethylene glycol 400, propylene glycol and water for injection.

What MIRANOST looks like and contents of the pack

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MIRANOST is a clear, colourless to yellowish coloured solution, free from visible particles.

MIRANOST is packed in a Type I clear glass vial with rubber stopper and a white unit dose nasal spray device supplied in boxes of 2 nasal spray units, each contained within an individual blister pack.

Holder of Certificate of Registration

CIPLA MEDPRO (PTY) LTD.

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Registration number(s)

58/2.5/0059

Access to the corresponding Professional Information

To access corresponding Professional Information, scan the QR Code below.

HC

PLACE HOLDER:

The QR Code to be generated and included after approval.