

## PATIENT MEDICATION INFORMATION

### READ THIS FOR SAFE AND EFFECTIVE USE OF YOUR MEDICINE

 Midazolam Injection USP

Midazolam Solution

Read this carefully before you start taking **Midazolam Injection USP** and each time afterward. This leaflet is a summary and will not tell you everything about this drug. Talk to your healthcare professional about your medical condition and treatment and ask if there is any new information about **Midazolam Injection USP**.

#### Serious Warnings and Precautions

**Serious Heart and Breathing Problems:** Serious, and sometimes fatal, heart and breathing problems have occurred in people taking Midazolam Injection USP. Midazolam Injection USP should only be used in a healthcare setting where you can be closely monitored and where there is access to oxygen and the appropriate medication and equipment required for resuscitation.

**Addiction, Abuse and Misuse:** Even if you are given Midazolam Injection USP exactly as prescribed, you are at risk for abuse, misuse, addiction, physical dependence and withdrawal. Abuse and misuse can result in an overdose or death, especially if you take Midazolam Injection USP with:

- opioids
- alcohol or
- illicit drugs

Your healthcare professional should:

- talk to you about the risks of treatment with Midazolam Injection USP as well as other treatment (including non-drug) options
- assess your risk for these behaviours before prescribing Midazolam Injection USP
- monitor you while you are taking Midazolam Injection USP for the signs and symptoms of misuse and abuse. If you feel like you are craving Midazolam Injection USP, or not using it as directed, talk to your healthcare professional right away.

Store Midazolam Injection USP in a secure place to avoid theft or misuse.

**Withdrawal:** If you suddenly stop taking Midazolam Injection USP, lower your dose too fast, or switch to another medication, you can experience severe or life-threatening withdrawal symptoms (see Other warnings you should know about)

- Always talk to your healthcare professional before stopping or lowering your Midazolam Injection USP or changing your medicine.

**Midazolam Injection USP with Opioids:** Taking Midazolam Injection USP with opioid medicines can cause:

- severe drowsiness

- **decreased awareness**
- **breathing problems**
- **coma**
- **death**

### **What is Midazolam Injection USP used for?**

- Midazolam Injection USP is used before surgery and other medical procedures. It helps to cause drowsiness, decrease anxiety, and to decrease your memory of the procedure. It is also used in patients in the ICU (Intensive Care Unit) who are sedated and on breathing machines.

If you are 65 years or older, talk to your healthcare professional before starting Midazolam Injection USP. Midazolam Injection USP may not be an effective treatment for you and you may be more sensitive to experiencing side effects.

### **How does Midazolam Injection USP work?**

Midazolam Injection USP belongs to a group of drugs called benzodiazepines. It works by calming the brain and nerves.

### **What are the ingredients in Midazolam Injection USP?**

Medicinal ingredients: midazolam

Non-medicinal ingredients: benzyl alcohol, disodium edetate, hydrochloric acid, sodium chloride and sodium hydroxide, water for injection

### **Midazolam Injection USP comes in the following dosage forms:**

Solution; 1 mg / mL or 5 mg / mL

### **Do not use Midazolam Injection USP if:**

- you are allergic (hypersensitive) to midazolam, benzodiazepines or any of the other ingredients in Midazolam Injection USP (See What are the ingredients in Midazolam Injection USP?)
- you have severe lung problems, such as chronic obstructive pulmonary disease (COPD)
- you have increased pressure in your eye (acute narrow angle glaucoma)

**To help avoid side effects and ensure proper use, talk to your healthcare professional before you take Midazolam Injection USP. Talk about any health conditions or problems you may have, including if you:**

- have heart or lung problems
- have liver or kidney problems
- have myasthenia gravis, a disease that causes muscle weakness
- have ever had problem with
  - substance abuse, including prescribed or illegal drugs, or
  - alcohol

- have ever had a seizure or convulsions (violent uncontrollable shaking of the body with or without loss of consciousness)
- have ever had hallucinations (seeing or hearing things that are not there) or other severe mental health problems
- have ever had skin problems
- have ever had stomach or gut problems
- have ever had severe allergic reactions
- have vision problems such as blurred vision
- are pregnant or planning to become pregnant
- are breastfeeding. Midazolam Injection USP passes into breastmilk.

**Other warnings you should know about:**

**Withdrawal:** If you suddenly stop your treatment, lower your dose too fast, or switch to another medication, you can experience withdrawal symptoms that can range from mild symptoms to severe or life threatening. Some of your withdrawal symptoms can last for months after you stop Midazolam Injection USP.

Your risk of going through withdrawal is higher if you are taking Midazolam Injection USP for a long time or at high doses. However, symptoms can still occur if you are taking Midazolam Injection USP as directed for a short period of time or slowly reducing the dose.

The symptoms of withdrawal often resemble the condition that you are being treated for. After stopping your treatment, it may be hard to tell if you are experiencing withdrawal or a return of your condition (relapse).

Tell your healthcare professional **right away** if you experience any symptoms of withdrawal after changing or stopping your treatment.

Severe symptoms of withdrawal include:

- feeling like you cannot move or respond (catatonia)
- severe confusion, shivering, irregular heart rate and excessive sweating (delirium tremens)
- feeling depressed
- feeling disconnected from reality (dissociation)
- seeing or hearing things that are not there (hallucinations)
- overactive behavior and thoughts (mania)
- believing in things that are not true (psychosis)
- convulsions (seizures), including some that do not stop
- thoughts or actions of suicide

For other symptoms of withdrawal, see the Serious side effects and what to do about them table (below).

To reduce your chances of going through withdrawal:

- always talk to your healthcare professional before stopping or reducing your dose of Midazolam Injection USP or changing medications
- always follow your healthcare professional's instructions on how to reduce your dose carefully and safely
- tell your healthcare professional right away if you experience any unusual symptoms after changing or stopping your treatment

**Midazolam Injection USP with Opioids:** Taking Midazolam Injection USP with opioid medicines can cause severe drowsiness and breathing problems.

**Tell your healthcare professional if you:**

- are taking opioid medicines
- are prescribed an opioid medicine after you start taking Midazolam Injection USP

**Driving and Using Machines:** Do NOT drive or operate heavy machinery or do tasks that require special attention until you know how taking an opioid medicine and Midazolam Injection USP affects you. Even if you are not taking Midazolam Injection USP with an opioid you should not drive or do other tasks that require attention for at least 24 hours after taking Midazolam Injection USP, or until all of the effects, such as drowsiness, have worn off.

**Falls and Fractures:** Benzodiazepines like Midazolam Injection USP can cause you to feel sleepy, dizzy, and affect your balance. This increases your risks of falling, which can cause fractures or other fall related-injuries especially if you:

- take other sedatives
- consume alcohol
- are elderly or
- have a condition that causes weakness or frailty.

**Tell your healthcare professional about all the medicines you take, including any drugs, vitamins, minerals, natural supplements or alternative medicines.**

#### **Serious Drug Interactions**

**Taking Midazolam Injection USP and opioids may cause:**

- severe drowsiness
- trouble breathing
- coma
- death

**The following may interact with Midazolam Injection USP:**

- barbiturates and other medicines that cause drowsiness or decrease anxiety
- medicines used to treat fungal infections, such as itraconazole and fluconazole
- erythromycin, an antibiotic used to treat bacterial infections
- saquinavir, a medicine used to treat HIV/AIDS
- sodium valproate, a medicine used to prevent seizures
- alcohol

### How to take Midazolam Injection USP:

- Midazolam Injection USP will be given to you either as an injection into your muscle or an injection directly into your vein
- Your healthcare professional will slowly decrease your dose and will tell you when to stop taking the medicine. Always follow your healthcare professional's instructions on how to lower your dose carefully and safely to avoid experiencing withdrawal symptoms.

### Usual dose:

Your healthcare professional will decide on the dose that is right for you based on your age, your weight and the type of medical procedure you are having.

### Overdose:

If you think you, or a person you are caring for, have taken too much Midazolam Injection USP, contact a healthcare professional, hospital emergency department, or regional poison control centre immediately, even if there are no symptoms.

### Missed Dose:

Midazolam Injection USP will be given to you in a healthcare setting. Your healthcare professional will make sure you do not miss a dose.

### What are possible side effects from using Midazolam Injection USP?

These are not all the possible side effects you may have when taking Midazolam Injection USP. If you experience any side effects not listed here, tell your healthcare professional.

Side effects may include:

- falls and fractures
- headache
- dizziness
- drowsiness
- feeling agitated
- confusion
- nausea, vomiting
- hiccups
- cough
- skin, rash especially in children

Serious side effects and what to do about them			
Symptom / effect	Talk to your healthcare professional		Stop taking drug and get immediate medical help
	Only if severe	In all cases	
UNKNOWN			

Serious side effects and what to do about them			
Symptom / effect	Talk to your healthcare professional		Stop taking drug and get immediate medical help
	Only if severe	In all cases	
<b>Overdose:</b> extreme sleepiness, confusion, slurred speech, slow reflexes, slow shallow breathing, coma, loss of balance and coordination, uncontrolled rolling of the eyes, and low blood pressure.			✓
<b>Respiratory Depression:</b> slow, shallow or weak breathing.			✓
<b>Withdrawal:</b> <b>Severe symptoms include:</b> <b>Catatonia:</b> feeling like you cannot move or respond <b>Delirium Tremens:</b> severe confusion, shivering, irregular heartrate and excessive sweating <b>Feeling depressed</b> <b>Dissociation:</b> feeling disconnected from reality <b>Hallucinations:</b> seeing or hearing things that are not there <b>Mania:</b> overactive behaviour and thoughts <b>Psychosis:</b> believing in things that are not true <b>Convulsions:</b> (seizures – including some that do not stop): loss of consciousness with uncontrollable shaking <b>Thoughts or actions of suicide</b> <b>Other symptoms include:</b> stomach cramps; trouble remembering or concentrating; diarrhea; feeling uneasy or restless; severe anxiety or panic-attacks; headache; sensitivity to light, noise or physical contact; shaking; vomiting; trouble sleeping; feeling irritable; muscle pain or stiffness; a burning or prickling feeling in the hands, arms, legs or feet; sweating.		✓	
<b>Allergic Reaction:</b> rash, hives, swelling of the face, lips, tongue or throat, difficulty swallowing or breathing.			✓

Serious side effects and what to do about them			
Symptom / effect	Talk to your healthcare professional		Stop taking drug and get immediate medical help
	Only if severe	In all cases	
<b>Injection Site Reaction:</b> pain, burning, redness, warmth or swelling at the injection site.		✓	

If you have a troublesome symptom or side effect that is not listed here or becomes bad enough to interfere with your daily activities, tell your healthcare professional.

### Reporting Side Effects

You can report any suspected side effects associated with the use of health products to Health Canada by:

- Visiting the Web page on Adverse Reaction Reporting (<https://www.canada.ca/en/health-canada/services/drugs-health-products/medeffect-canada/adverse-reaction-reporting.html>) for information on how to report online, by mail or by fax; or
- Calling toll-free at 1-866-234-2345.

*NOTE: Contact your health professional if you need information about how to manage your side effects. The Canada Vigilance Program does not provide medical advice.*

### Storage:

- Keep out of reach and sight of children.
- Store between 20°C and 25°C. Protect from light and freezing. Discard unused portion 28 days after initial puncture.

### If you want more information about Midazolam Injection USP:

- Talk to your healthcare professional
- Find the full product monograph that is prepared for healthcare professionals and includes this Patient Medication Information by visiting the Health Canada website: (<https://www.canada.ca/en/health-canada/services/drugs-health-products/drug-products/drug-product-database.html>); <https://www.pfizer.ca/>, or by calling 1-800-463-6001.

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