

**READ THIS FOR SAFE AND EFFECTIVE USE OF YOUR MEDICINE**  
**PATIENT MEDICATION INFORMATION**

**® FENTANYL CITRATE INJECTION SDZ**  
**(Fentanyl Citrate Injection, USP)**  
(Fentanyl 50 mcg/mL as fentanyl citrate)

**® FENTANYL CITRATE INJECTION USP**  
(Fentanyl 50 mcg/mL as fentanyl citrate)

Read this carefully before you start taking Fentanyl Citrate Injection SDZ or Fentanyl Citrate Injection USP. This leaflet is a summary and will not tell you everything about these drugs. Talk to your healthcare professional about your medical condition and treatment and ask if there is any new information about Fentanyl Citrate Injection SDZ or Fentanyl Citrate Injection USP.

**Serious Warnings and Precautions**

- **Even if you take Fentanyl Citrate Injection SDZ or Fentanyl Citrate Injection USP as prescribed you are at a risk for opioid addiction, abuse and misuse. This can lead to overdose and death.**
- **You may get life-threatening breathing problems while taking Fentanyl Citrate Injection SDZ or Fentanyl Citrate Injection USP. This is less likely to happen if you take it as prescribed by your doctor. Babies are at risk of life-threatening breathing problems if their mothers take opioids while pregnant or nursing.**
- **You should never give anyone your Fentanyl Citrate Injection SDZ or Fentanyl Citrate Injection USP. They could die from taking it. If a person has not been prescribed Fentanyl Citrate Injection SDZ or Fentanyl Citrate Injection USP, taking even one dose can cause a fatal overdose. This is especially true for children.**
- **If you took Fentanyl Citrate Injection SDZ or Fentanyl Citrate Injection USP while you were pregnant, whether for short or long periods of time or in small or large doses, your baby can suffer life-threatening withdrawal symptoms after birth. This can occur in the days after birth and for up to 4 weeks after delivery. If your baby has any of the following symptoms:**
  - **has changes in their breathing (such as weak, difficult or fast breathing)**
  - **is unusually difficult to comfort**
  - **has tremors (shakiness)**
  - **has increased stools, sneezing, yawning, vomiting, or fever****Seek immediate medical help for your baby.**

- **Fentanyl Citrate Injection SDZ and Fentanyl Citrate Injection USP should only be administered by persons with the appropriate training and experience with these kind of drugs.**
- **Complete resuscitation (life-saving) equipment and an antidote to rapidly counteract the effects of the drug should always be available.**
- **Taking Fentanyl Citrate Injection SDZ or Fentanyl Citrate Injection USP with other opioid medicines, benzodiazepines, alcohol, or other central nervous system depressants (including street drugs) can cause severe drowsiness, decreased awareness, breathing problems, coma, and death.**

### **What are Fentanyl Citrate Injection SDZ and Fentanyl Citrate Injection USP used for?**

Fentanyl Citrate Injection SDZ and Fentanyl Citrate injection USP are indicated for the following uses:

When injected in a vein

- For pain relief of short duration during prior to, during and immediately after general or regional anesthesia.

When injected in the spine

- For pain relief after surgery, and during labour and vaginal delivery.

### **How do Fentanyl Citrate Injection SDZ and Fentanyl Citrate Injection USP work?**

Fentanyl Citrate Injection SDZ and Fentanyl Citrate Injection USP are painkillers belonging to the class of drugs known as opioids. They relieve pain by acting on specific nerve cells of the spinal cord and brain.

Fentanyl Citrate Injection SDZ and Fentanyl Citrate Injection USP will provide pain relief when injected in a vein prior to, during and immediately after general or regional anesthesia. When injected in the spine after surgery, during labour and vaginal delivery, it provides pain relief.

### **What are the ingredients in Fentanyl Citrate Injection SDZ and Fentanyl Citrate Injection USP?**

Each mL of Fentanyl Citrate Injection SDZ solution contains: fentanyl 50 mcg (as citrate), sodium chloride, hydrochloric acid and/or sodium hydroxide to adjust pH and water for injection.

Each mL of Fentanyl Citrate Injection USP solution contains: fentanyl 50 mcg (as citrate), citric acid and/or sodium hydroxide to adjust pH and water for injection.

### **Fentanyl Citrate Injection SDZ and Fentanyl Citrate Injection USP come in the following dosage forms:**

Fentanyl Citrate Injection SDZ is supplied in 2 mL ampoules, boxes of 10 and 10 mL ampoules, boxes of 5.

Fentanyl Citrate Injection USP is supplied in 2 mL ampoules, boxes of 10.

Fentanyl Citrate Injection USP is also supplied in 5 mL, 10 mL and 20 mL single use glass vials, boxes of 5, and 50 mL Pharmacy Bulk Vials, boxes of 1.

**Do not use Fentanyl Citrate Injection SDZ or Fentanyl Citrate Injection USP if:**

- your doctor did not prescribe it for you
- you are allergic to fentanyl or any of the other ingredients in Fentanyl Citrate Injection SDZ or Fentanyl Citrate Injection USP
- you can control your pain by the occasional use of other pain medications. This includes those available without a prescription
- you have severe asthma, trouble breathing, or other breathing problems
- you have any heart problems
- you have bowel blockage or narrowing of the stomach or intestines
- you have severe pain in your abdomen
- you have a head injury
- you are at risk for seizures
- you suffer from alcoholism
- you are taking or have taken within the past 2 weeks a Monoamine Oxidase inhibitor (MAOi) (such as phenelzine sulphate, tranylcypromine sulphate, moclobemide or selegiline)
- you are going to have, or recently had, a planned surgery

To prevent breathing problems in the newborn baby, fentanyl should not be injected into a vein (intravenous use) during labour or cesarean section before the umbilical cord has been cut. Injection around the spinal cord (epidural use), however, is permitted.

Fentanyl Citrate Injection SDZ or Fentanyl Citrate Injection USP should not be injected around the spinal cord (epidural use) if there is shock, severe bleeding, systemic infection, or infection around the injection site. This use should also be avoided if you bleed easily or you are taking a blood-thinner.

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

- have a history of illicit or prescription drug or alcohol abuse
- have past or current depression
- suffer from chronic or severe constipation
- are an elderly person

- have a condition with any part of your body, such as your heart, lung, liver, or thyroid
- have problems with your adrenal or prostate gland
- are taking any medication, such as blood thinners, and/or pain killers
- are pregnant or planning to become pregnant
- have a known allergic reaction to this drug or any other pain medications or any other general anesthetics
- have had a head injury (history and/or current), or if you experience difficulties breathing
- suffer from migraines
- have severe kidney, liver, lung disease
- have heart disease
- have low blood pressure
- have, or had in the past, hallucinations or other severe mental problems

**Other warnings you should know about:**

**Opioid dependence and addiction:** There are important differences between physical dependence and addiction. It is important that you talk to your doctor if you have questions or concerns about abuse, addiction or physical dependence.

**Pregnancy, nursing, labour and delivery:**

Opioids can be transferred to your baby while still in the womb, or through breast milk. Fentanyl Citrate Injection SDZ or Fentanyl Citrate Injection USP can then cause life-threatening breathing problems in your unborn baby or nursing infant. Your doctor will determine if the benefits of using Fentanyl Citrate Injection SDZ or Fentanyl Citrate Injection USP outweigh the risks to your unborn baby or nursing infant.

If you are pregnant and are taking Fentanyl Citrate Injection SDZ or Fentanyl Citrate Injection USP, it is important that you don't stop taking your medication all of a sudden. If you do, it can cause a miscarriage or a still-birth. Your doctor will monitor and guide you on how to slowly stop taking Fentanyl Citrate Injection SDZ or Fentanyl Citrate Injection USP. This may help avoid serious harm to your unborn baby.

**Driving and using machines:** Before you do tasks which may require special attention, you should wait until you know how you react to Fentanyl Citrate Injection SDZ or Fentanyl Citrate Injection USP. Fentanyl Citrate Injection SDZ and Fentanyl Citrate Injection USP can cause:

- drowsiness
- dizziness or
- lightheadedness

This can usually occur after you take your first dose and when your dose is increased.

**Disorder of the adrenal gland:** You may develop a disorder of the adrenal gland called adrenal insufficiency. This means that your adrenal gland is not making enough of certain hormones. You may experience symptoms such as:

- nausea, vomiting
- feeling tired, weak or dizzy
- decreased appetite

You may be more likely to have problems with your adrenal gland if you have been taking opioids for longer than one month. Your doctor may do tests, give you another medication, and slowly take you off Fentanyl Citrate Injection SDZ or Fentanyl Citrate Injection USP.

**Serotonin Syndrome:** Fentanyl Citrate Injection SDZ or Fentanyl Citrate Injection USP can cause Serotonin Syndrome, a rare but potentially life-threatening condition. It can cause serious changes in how your brain, muscles and digestive system work. You may develop Serotonin Syndrome if you take Fentanyl Citrate Injection SDZ or Fentanyl Citrate Injection USP with certain anti-depressants or migraine medications.

Serotonin Syndrome symptoms include:

- fever, sweating, shivering, diarrhea, nausea, vomiting;
- muscle shakes, jerks, twitches or stiffness, overactive reflexes, loss of coordination;
- fast heartbeat, changes in blood pressure;
- confusion, agitation, restlessness, hallucinations, mood changes, unconsciousness, and coma.

**Sexual Function/Reproduction:** Long term use of opioids may lead to a decrease in sex hormone levels. It may also lead to low libido (desire to have sex), erectile dysfunction or being infertile.

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

**The following may interact with Fentanyl Citrate Injection SDZ or Fentanyl Citrate Injection USP:**

- Alcohol. This includes prescription and non-prescription medications that contain alcohol. **Do not** drink alcohol while you are taking Fentanyl Citrate Injection SDZ or Fentanyl Citrate Injection USP. It can lead to:
  - drowsiness
  - unusually slow or weak breathing
  - serious side effects or
  - a fatal overdose
- other sedative drugs which may enhance the drowsiness caused by Fentanyl Citrate Injection SDZ or Fentanyl Citrate Injection USP
- other opioid analgesics (drugs used to treat pain)
- general anesthetics (drugs used during surgery)
- benzodiazepines (drugs used to help you sleep or that help reduce anxiety)
- antidepressants (for depression and mood disorders). **Do not** take Fentanyl Citrate Injection SDZ or Fentanyl Citrate Injection USP with MAO inhibitors (MAOI) or if you have taken MAOI's in the last 14 days.
- drugs used to treat serious mental or emotional disorders (such as schizophrenia)
- antihistamines (drugs used to treat allergies)
- anti-emetics (drugs used for the prevention of vomiting)

- drugs used to treat muscle spasms and back pain
- anti-fungal drugs (used to treat fungal infections)
- anti-retroviral drugs (used to treat viral infections)
- some heart medication (such as beta blockers)
- tranquilizers
- grapefruit juice
- drugs used to treat migraines (e.g. triptans)
- St. John's Wort

Your doctor should tell you what medication you may or may not use after your surgery or childbirth.

Before taking Fentanyl Citrate Injection SDZ or Fentanyl Citrate Injection USP, tell your doctor about any other medications that you are using including certain antidepressants (selective serotonin reuptake inhibitors (SSRI) and serotonin/norepinephrine reuptake inhibitors (SNRI).

**After surgery – Side effects and what to do with them:**

In rare cases, muscle stiffness and swollen face have been reported. Call your doctor if you have these conditions.

Since Fentanyl Citrate Injection SDZ and Fentanyl Citrate Injection USP are commonly used together with general anesthetics and other drugs, other side effects may occur.

This is not a complete list of side effects. For any unexpected effects while taking Fentanyl Citrate Injection SDZ or Fentanyl Citrate Injection USP, contact your doctor or pharmacist.

**How to take Fentanyl Citrate Injection SDZ or Fentanyl Citrate Injection USP:**

Fentanyl Citrate Injection SDZ and Fentanyl Citrate Injection USP can only be used by a doctor in a facility with life-saving equipment.

**Usual Starting Dose:**

Your dose is tailored/personalized just for you. The dose given to you by your doctor will depend on such factors as how much you weigh, your current health status, any diseases you may currently have, and the kind of surgical procedure you will be undergoing.

Your doctor will prescribe the lowest dose that works to control your pain. It is recommended that you only take Fentanyl Citrate Injection SDZ or Fentanyl Citrate Injection USP for up to 7 days. If you need to take Fentanyl Citrate Injection SDZ or Fentanyl Citrate Injection USP for longer, your doctor will determine the best dose for you to lower the risk of side effects and overdose. Higher doses can lead to more side effects and a greater chance of overdose.

Review your pain regularly with your doctor to determine if you still need Fentanyl Citrate Injection SDZ or Fentanyl Citrate Injection USP. Be sure to use Fentanyl Citrate Injection SDZ or Fentanyl Citrate Injection USP only for the condition for which it was prescribed.

If your pain increases or you develop any side effect as a result of taking Fentanyl Citrate Injection SDZ or Fentanyl Citrate Injection USP tell your doctor immediately.

### **Stopping your Medication**

If you have been taking Fentanyl Citrate Injection SDZ or Fentanyl Citrate Injection USP for more than a few days you should not stop taking it all of a sudden. Your doctor will monitor and guide you on how to slowly stop taking Fentanyl Citrate Injection SDZ or Fentanyl Citrate Injection USP. You should do it slowly to avoid uncomfortable symptoms such as having:

- body aches
- diarrhea
- goosebumps
- loss of appetite
- nausea
- feeling nervous or restless
- runny nose
- sneezing
- tremors or shivering
- stomach cramps
- rapid heart rate (tachycardia)
- having trouble sleeping
- an unusual increase in sweating
- heart palpitations
- an unexplained fever
- weakness
- yawning

By reducing or stopping your opioid treatment, your body will become less used to opioids. If you start treatment again, you will need to start at the lowest dose. You may overdose if you restart at the last dose you took before you slowly stopped taking Fentanyl Citrate Injection SDZ or Fentanyl Citrate Injection USP.

### **Overdose:**

If you think you have taken too much Fentanyl Citrate Injection SDZ or Fentanyl Citrate Injection USP contact your healthcare professional, hospital emergency department or regional Poison Control Centre immediately, even if there are no symptoms.

Signs of overdose may include:

- unusually slow or weak breathing
- dizziness
- confusion

- extreme drowsiness

**Missed Dose:**

If you miss one dose, take it as soon as possible. However, if it is almost time for your next dose, then skip the missed dose. Do not take two doses at once. If you miss several doses in a row, talk to your doctor before restarting your medication.

**What are possible side effects from using Fentanyl Citrate Injection SDZ or Fentanyl Citrate Injection USP?**

These are not all the possible side effects you may feel when taking Fentanyl Citrate Injection SDZ or Fentanyl Citrate Injection USP. If you experience any side effects not listed here, contact your healthcare professional.

Side effects may include:

- Drowsiness
- Insomnia
- Dizziness
- Fainting
- Nausea, vomiting, or a poor appetite
- Dry mouth
- Headache
- Problems with vision
- Weakness, uncoordinated muscle movement
- Itching
- Sweating
- Constipation
- Low sex drive, impotence (erectile dysfunction), infertility

Talk with your doctor or pharmacist about ways to prevent constipation when you start using Fentanyl Citrate Injection SDZ or Fentanyl Citrate Injection USP.

<b>Serious side effects and what to do about them</b>			
Symptom / effect	Talk to your healthcare professional		Stop taking drug and get immediate medical help
	Only if severe	In all cases	
<b>RARE</b>  <b>Overdose:</b> hallucinations, confusion, inability to walk normally, slow or weak breathing, extreme sleepiness, sedation, or dizziness, floppy			✓



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	
muscles/low muscle tone cold and clammy skin.			
<b>Respiratory Depression:</b> slow, shallow or weak breathing.			✓
<b>Allergic Reaction:</b> rash, hives, swelling of the face, lips, tongue or throat, difficulty swallowing or breathing.			✓
<b>Bowel Blockage (impaction):</b> Abdominal pain, severe constipation, nausea			✓
<b>Withdrawal:</b> nausea, vomiting, diarrhea, anxiety, shivering, cold and clammy skin, body aches, loss of appetite, sweating.		✓	
<b>Fast, Slow or Irregular Heartbeat:</b> heart palpitations.		✓	
<b>Low Blood Pressure:</b> dizziness, fainting, light-headedness.	✓		
<b>Serotonin Syndrome:</b> agitation or restlessness, loss of muscle control or muscle twitching, tremor, diarrhea.			✓
<b>High blood pressure:</b> headache, dizziness.			✓
<b>Difficulty Urinating</b>			✓

If you have a troublesome symptom or side effect that is not listed here or becomes bad enough to interfere with your daily activities, talk to 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 (<http://www.hc-sc.gc.ca/dhp-mps/medeff/report-declaration/index-eng.php>) 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 unused or expired Fentanyl Citrate Injection SDZ or Fentanyl Citrate Injection USP in a secure place to prevent theft, misuse or accidental exposure.**
- Keep out of the reach of children.
- Store between 15 and 30°C. Protect from light. Protect from freezing. Discard unused portion.
- **Keep Fentanyl Citrate Injection SDZ and Fentanyl Citrate Injection USP under lock, out of sight and reach of children and pets.**
- **Never take medicine in front of small children as they will want to copy you. Accidental ingestion by a child is dangerous and may result in death. If a child accidentally takes Fentanyl Citrate Injection SDZ and Fentanyl Citrate Injection USP, get emergency help right away.**

### **Disposal:**

**Fentanyl Citrate Injection SDZ and Fentanyl Citrate Injection USP should never be thrown into household trash, where children and pets may find it.** It should be returned to a pharmacy for proper disposal.

If you want more information about Fentanyl Citrate Injection SDZ and Fentanyl Citrate 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 <http://www.canada.ca/en/health-canada/services/drugs-health-products/drug-products/drug-product-database.html>; or by calling Sandoz Canada Inc. at 1-800-361-3062.

or by written request at:

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