

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

**^NREMIFENTANIL FOR INJECTION
1 mg/vial, 2mg/vial of remifentanil**

Read this carefully before you start taking Remifentanil for Injection and each time you get a refill. 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 Remifentanil for Injection.

Serious Warnings and Precautions

- **Even if you take Remifentanil for Injection 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 Remifentanil for Injection. 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 Remifentanil for Injection. They could die from taking it. If a person has not been prescribed Remifentanil for Injection taking even one dose can cause a fatal overdose. This is especially true for children.**
- **If you took Remifentanil for Injection 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.

- **Taking Remifentanil for Injection 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 is Remifentanil for Injection is used for:

Remifentanil for Injection is a pain medication. It is given along with other drugs used for anesthesia by your doctor. It may be given to you.

- before and/ or during surgery;
- if you are undergoing painful medical procedures;

How does Remifentanil for Injection work?

Remifentanil for Injection is a fast acting pain relief medication and belongs to a class of medicines known as opioids. It provides pain relief for a short period of time. It relieves pain by acting on specific nerve cells of the spinal cord and brain.

What are the ingredients in Remifentanil for Injection?

Medicinal Ingredients: Remifentanil hydrochloride

Non-medicinal ingredients: Glycine and hydrochloric acid (adjust pH).

Remifentanil for Injection comes in the following dosage forms:

Lyophilized Powder for Injection, 1 mg and 2 mg of remifentanil in a 4mL vials.

Do not use Remifentanil for Injection if:

- your doctor did not prescribe it for you
- you are allergic to remifentanil hydrochloride or any of the other ingredients in Remifentanil for Injection
- 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.
- you are pregnant or planning to become pregnant or you are in labour
- you are breastfeeding

To help avoid side effects and ensure proper use, talk to your healthcare professional before you take Remifentanil for Injection. 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 severe kidney, liver or lung disease
- have heart disease
- have low blood pressure
- have past or current depression
- suffer from chronic or severe constipation
- have problems with your adrenal or prostate gland
- have, or had in the past hallucinations or other severe mental problems
- suffer from migraines
- are planning to become pregnant.

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

If you are pregnant and are taking Remifentanil for Injection, 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 Remifentanil for Injection. 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 Remifentanil for Injection.

Remifentanil for Injection 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 Remifentanil for Injection.

Serotonin Syndrome:

Remifentanil for Injection 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 Remifentanil for Injection 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 Remifentanil for Injection:

- **Alcohol. This includes prescription and non-prescription medications that contain alcohol. Do not drink alcohol while you are taking Remifentanil for Injection. 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 Remifentanil for Injection
- 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 Remifentanyl for Injection 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
- some heart medication (such as beta blockers)
- drugs used to treat migraines (e.g. triptans)
- St John's Wort

How to take Remifentanyl for Injection:

Remifentanyl for Injection is given via an injection.

You should be given it:

- only in a hospital or clinic that has the proper monitoring and support equipment in place.
- by a healthcare professional that has been specifically trained in the use of intravenous anesthetics.

Usual dose:

Your doctor will decide the best dose for you. It will depend on your age, weight, your health, medications you are currently taking and the type of surgery you are having.

Overdose:

If you think you have taken too much Remifentanyl for Injection, 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

What are possible side effects from using Remifentanyl for Injection ?

These are not all the possible side effects you may feel when taking Remifentanyl for Injection. 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
- High or low blood pressure
- Excessive sweating
- feeling of intense happiness or excitement (euphoria)
- feeling agitated
- crying
- headache
- trouble with your vision
- sleep apnea (a sleep disorder where your breathing is interrupted during sleep)
- pain at the injection site
- feeling tired
- chills
- low sex drive, impotence (erectile dysfunction), infertility

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	
COMMON			
Allergic reaction: Itching or hives, swelling in your face or hands, swelling or tingling in your mouth or throat, chest tightness, trouble breathing		x	
Drowsiness, dizziness.		x	
Fast, slow, or uneven heartbeat.		x	
Severe nausea or vomiting.		x	
Stiffness in the muscles of your neck, chest, hands, or legs.		x	
Trouble breathing, or chest tightness.		x	
UNCOMMON	x		
Mild skin rash or itching.	x		
Twitching or muscle movements you cannot control.	x		
Pain, itching, burning, swelling, or lump under your skin where the needle is placed.	x		
Twitching or muscle movements you cannot control.	x		
RARE			
Overdose: hallucinations, confusion, inability to walk normally, slow or weak breathing, extreme sleepiness, sedation, or dizziness, floppy muscles/low muscle tone cold and clammy skin.			x
Respiratory Depression: Slow, shallow or weak breathing.			x
Allergic Reaction: rash, hives, swelling of the face, lips, tongue or throat, difficulty swallowing or breathing			x
Bowel Blockage (impaction): abdominal pain, severe constipation, nausea			x
Withdrawal: nausea, vomiting, diarrhea, anxiety, shivering, cold and clammy skin, body aches, loss of appetite, sweating.		x	

Serious side effects and what to do about them			
Fast, Slow or Irregular Heartbeat: heart palpitations.		x	
Low Blood Pressure: dizziness, fainting, light-headedness.	x		
Serotonin Syndrome: agitation or restlessness, loss of muscle control or muscle twitching, tremor, diarrhea			x

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:

Remifentanil for Injection should be stored between 2°C to 25°C.

If you want more information about Remifentanil for Injection:

- 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/drugproducts/](https://www.canada.ca/en/health-canada/services/drugs-health-products/drugproducts/drug-product-database.html)); the manufacturer's website www.sandoz.ca, or by calling 1-800-361-3062

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