

READ THIS FOR SAFE AND EFFECTIVE USE OF YOUR MEDICINE

PATIENT MEDICATION INFORMATION

HYDROmorphone Hydrochloride Injection USP

(10 mg/mL Sterile Solution for Injection)

Read this carefully before you start taking HYDROmorphone Hydrochloride Injection USP 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 HYDROmorphone Hydrochloride Injection USP.

Serious Warnings and Precautions

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

HYDROmorphone Hydrochloride Injection USP is an injection containing HYDROmorphone (an opioid analgesic) used to control pain.

How does HYDROmorphone Hydrochloride Injection USP work?

HYDROmorphone Hydrochloride Injection USP is a pain medication belonging to the class of drugs known as opioids, which includes codeine, fentanyl, morphine and oxycodone. It relieves pain by acting on specific nerve cells of the spinal cord and brain.

HYDROmorphone Hydrochloride Injection USP is used to treat severe pain in patients who need an opioid administered by injection. This is given under the skin, into the muscle or vein in doses or concentrations that are higher than those usually needed.

What are the ingredients in HYDROmorphone Hydrochloride Injection USP?

Medicinal ingredient: HYDROmorphone Hydrochloride

Non-medicinal ingredients: citric acid, sodium citrate.

HYDROmorphone Hydrochloride Injection USP comes in the following dosage forms:

Solution for injection: 1 mL, 5 mL and 50 mL single-use vials.

Do not use HYDROmorphone Hydrochloride Injection USP if:

- your doctor did not prescribe it for you
- you are allergic to HYDROmorphone, other opioids, or any of the other ingredients in HYDROmorphone Hydrochloride Injection USP (see **What the non-medicinal ingredients are:**)
- 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 or 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 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 HYDROmorphone Hydrochloride 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 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 thyroid, adrenal or prostate gland
- have, or had in the past hallucinations or other severe mental problems
- suffer from migraines
- are pregnant or 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:

Do not use HYDROmorphone Hydrochloride Injection USP while pregnant, nursing, during labour or delivery. Opioids can be transferred to your baby through breast milk, or while still in the womb. HYDROmorphone Hydrochloride Injection USP can then cause life-threatening breathing problems in your unborn baby or nursing infant.

If you are pregnant and are taking HYDROmorphone Hydrochloride 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 HYDROmorphone Hydrochloride 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 HYDROmorphone Hydrochloride Injection USP. HYDROmorphone Hydrochloride Injection USP can cause:

- drowsiness
- dizziness or
- light headedness

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 HYDROmorphone Hydrochloride Injection USP.

Serotonin syndrome: HYDROmorphone Hydrochloride 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 HYDROmorphone Hydrochloride 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 HYDROmorphone Hydrochloride Injection USP:

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

How to take HYDROmorphone Hydrochloride Injection USP:

HYDROmorphone Hydrochloride Injection USP should be visually inspected prior to use. Only clear solutions free from particles should be used. The injection should be given immediately after opening the vial. Once opened, any unused portion should be discarded.

HYDROmorphone Hydrochloride Injection USP is a highly concentrated solution of hydromorphone hydrochloride. It should be used only in opioid tolerant patients requiring high doses or high concentrations of opioid agonists. Do not confuse HYDROmorphone Hydrochloride Injection USP with the lower concentration of HYDROmorphone since overdosage and death could result.

Usual Adult Starting Dose:

Your dose is tailored/personalized just for you. Be sure to follow your doctor's dosing instructions exactly. Do not increase or decrease your dose without consulting your doctor.

Your doctor will prescribe the lowest dose that works to control your pain. It is recommended that you only take HYDROmorphone Hydrochloride Injection USP for up to 7 days. If you need to take HYDROmorphone Hydrochloride 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 HYDROmorphone Hydrochloride Injection USP. Be sure to use HYDROmorphone Hydrochloride 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 HYDROmorphone Hydrochloride Injection USP, tell your doctor immediately.

Stopping your Medication:

If you have been taking HYDROmorphone Hydrochloride 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 HYDROmorphone Hydrochloride 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 HYDROmorphone Hydrochloride Injection USP.

Refilling your Prescription for HYDROmorphone Hydrochloride Injection USP:

A new written prescription is required from your doctor each time you need more HYDROmorphone Hydrochloride Injection USP. Therefore, it is important that you contact your doctor before your current supply runs out.

Only obtain prescriptions for this medication from the doctor in charge of your treatment. Do not seek prescriptions from other doctors unless you switch to another doctor for your pain management.

Overdose:

If you think you have taken too much HYDROmorphone Hydrochloride 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:

Your doctor will tell you what to do if you miss the 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 HYDROmorphone Hydrochloride Injection USP?

These are not all the possible side effects you may feel when taking HYDROmorphone Hydrochloride 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
- Lack of muscle strength
- Itching
- Light headedness
- Sweating
- Constipation
- Confusion
- Anxiety
- Abdominal pain
- Injection site reaction
- Low sex drive, impotence (erectile dysfunction), infertility

Talk with your doctor or pharmacist about ways to prevent constipation when you start using HYDROmorphone Hydrochloride Injection USP.

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

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

We encourage you to report serious or unexpected side effects to Health Canada. The information is used to check for new safety concerns about health products. As a consumer, your report contributes to the safe use of health products for everyone.

3 ways to report:

- Online at MedEffect: <https://www.canada.ca/en/health-canada/services/drugs-health-products/medeffect-canada.html>

- By calling 1-866-234-2345 (toll-free);

- By completing a Consumer Side Effect Reporting Form and sending it by:

- Fax to 1-866-678-6789 (toll-free), or
- Mail to: Canada Vigilance Program
Health Canada, Postal Locator 1908C
Ottawa, ON
K1A 0K9

Postage paid labels and the Consumer Side Effect Reporting Form are available at MedEffect (<https://www.canada.ca/en/health-canada/services/drugs-health-products/medeffect-canada.html>).

NOTE: Should you require information related to the management of side effects, contact your health professional. The Canada Vigilance Program does not provide medical advice.

Storage:

- **Keep unused or expired HYDROmorphone Hydrochloride Injection USP in a secure place to prevent theft, misuse or accidental exposure.**
- Store vials between 20°C and 25°C. Protect from light and freezing. Do not use beyond the expiry date indicated on the label.
- **Keep HYDROmorphone Hydrochloride 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 HYDROmorphone Hydrochloride Injection USP, get emergency help right away.**

Parenteral drug products should be inspected visually for particulate matter and discoloration prior to administration, whenever solution and container permit.

Disposal:

HYDROmorphone Hydrochloride 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 HYDROmorphone Hydrochloride Injection USP:

- Talk to your healthcare professional
- Find the full Prescribing Information 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](#)); the manufacturer's website www.pfizer.ca, or by calling 1-800-463-6001.

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