

PATIENT MEDICATION INFORMATION

READ THIS FOR SAFE AND EFFECTIVE USE OF YOUR MEDICINE

^NHYDROMORPH CONTIN®

HYDROmorphone Hydrochloride Controlled Release Capsules

Read this carefully before you start taking **HYDROMORPH CONTIN** 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 **HYDROMORPH CONTIN**.

Serious Warnings and Precautions

- Even if you take HYDROMORPH CONTIN as prescribed you are at risk for opioid addiction, abuse, and misuse. This can lead to overdose and death. To understand your risk of opioid addiction, abuse, and misuse you should speak to your health care professional.
- Life-threatening breathing problems can happen while taking HYDROMORPH CONTIN, especially if not taken as directed. Babies are at risk of life-threatening breathing problems if their mothers take opioids while pregnant or nursing.
- You should never give anyone your HYDROMORPH CONTIN. They could die from taking it. If a person has not been prescribed HYDROMORPH CONTIN, taking even one dose can cause a fatal overdose. This is especially true for children and for an adult who is not already taking opioids continuously.
- If you took HYDROMORPH CONTIN 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 feverSeek immediate medical help for your baby.
- Taking HYDROMORPH CONTIN 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 HYDROMORPH CONTIN used for?

HYDROMORPH CONTIN is used for the long-term management of pain, when:

- the pain is severe enough to require daily, around-the-clock pain medication
- the health care professional determines that other treatment options are not able to effectively manage your pain

HYDROMORPH CONTIN is NOT used (“as needed”) to treat pain that you only have once in a while.

How does HYDROMORPH CONTIN work?

HYDROMORPH CONTIN is an oral controlled release capsule that slowly releases HYDROmorphone over

a 12 hour period.

HYDROMORPH CONTIN contains HYDROmorphone which is a pain medication belonging to the class of medicines 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.

What are the ingredients in HYDROMORPH CONTIN?

Medicinal ingredient: HYDROmorphone hydrochloride

Non-medicinal ingredients: Colloidal silicon dioxide, dibutyl sebacate, ethyl cellulose, hydroxypropyl methylcellulose, and microcrystalline cellulose.

In addition, the capsule shells contain the following ingredients:

All capsules: gelatin, titanium dioxide

3 mg: D&C Yellow No.10, FD&C Green No.3

4.5 mg: FD&C Blue No.1, FD&C Red No.3

6 mg: D&C Red No.28, FD&C Blue No.1, FD&C Red No.40

9 mg: FD&C Blue No.1

10 mg: none

12 mg: D&C Red No.28, D&C Yellow No.10, FD&C Blue No.1, FD&C Red No.40

18 mg: yellow iron oxide

20 mg: FD&C Blue No.1

24 mg: black iron oxide

30 mg: FD&C Red No.3, red iron oxide, yellow iron oxide

HYDROMORPH CONTIN comes in the following dosage forms:

Controlled Release Capsules: 3 mg, 4.5 mg, 6 mg, 9 mg, 10 mg, 12 mg, 18 mg, 20 mg, 24 mg and 30 mg

Do not use HYDROMORPH CONTIN if:

- your health care professional did not prescribe it for you.
- you are allergic to HYDROmorphone, other opioids, or any of the other ingredients of HYDROMORPH CONTIN (see What are the ingredients in HYDROMORPH CONTIN?).
- you have mild or short term pain that can be controlled by the occasional use of pain medications, including those available without a prescription.
- you have severe asthma, trouble breathing, or other lung problems.
- you have any heart problems.
- you have a bowel blockage or narrowing of the stomach or intestines.
- you have a condition where the bowel does not work properly (ileus) or have severe pain in your abdomen.
- you have increased pressure in your skull or have a head injury.
- you have epilepsy (seizures) or a history with epilepsy.
- you have a brain tumor.
- you suffer from alcoholism or alcohol withdrawal.
- you are taking or have taken within the past 2 weeks a Monoamine Oxidase Inhibitors (MAOIs) medication (e.g., phenelzine sulfate, tranylcypromine sulfate, moclobemide or selegiline).
- you are pregnant or plan to become pregnant or you are in labour.
- you are breastfeeding.
- you are under 18 years of age.
- you are going to have a surgery or operation or have had a surgery in the last 24 hours.

To help avoid side effects and ensure proper use, talk to your healthcare professional before you take

HYDROMORPH CONTIN. 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 been told you are at risk of having heart problems or seizures.
- have heart disease.
- have low blood pressure.
- have a history of sleep apnea.
- Have had problems with your mood (such as depression or anxiety), hallucinations, or other mental health problems.
- have problems with your thyroid, adrenal or prostate gland.
- suffer from chronic or severe constipation.
- suffer from migraines.
- are pregnant or planning to become pregnant or are in labour.
- are breastfeeding or planning to breastfeed.
- have a sleep disorder which causes pauses in breathing or shallow breathing while sleeping (sleep apnea).
- are planning on drinking alcohol. Drinking alcohol while taking HYDROMORPH CONTIN may cause dangerous side effects, including death. Do NOT drink alcohol while taking HYDROMORPH CONTIN.
- have a condition that causes weakness or frailty.

Other warnings you should know about:

Opioid dependence and addiction: Like any opioid, HYDROMORPH CONTIN may cause mental and physical dependence. Hydromorphone hydrochloride also has the potential to cause addiction. There are important differences between physical dependence and addiction. Tolerance means that, over time, a higher dose may be needed to get the same level of pain relief. It is important that you talk to your healthcare professional if you have questions or concerns about addiction, physical dependence, or tolerance. Your healthcare professional should prescribe and administer HYDROMORPH CONTIN with the same degree of caution appropriate to the use of other oral opioid medications. It is not recommended to use these products for a long period of time.

Pregnancy, nursing, labour and delivery: Do not use HYDROMORPH CONTIN while pregnant, nursing, during labour or delivery. Opioids can be transferred to your baby through breast milk, or while still in the womb. HYDROMORPH CONTIN can then cause life-threatening breathing problems in your unborn baby or nursing infant.

If you are pregnant and are taking HYDROMORPH CONTIN, 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 health care professional will monitor and guide you on how to slowly stop taking HYDROMORPH CONTIN. 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 HYDROMORPH CONTIN. HYDROMORPH CONTIN can cause:

- drowsiness
- dizziness
- 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 healthcare professional may do tests, give you another medication, and slowly take you off HYDROMORPH CONTIN.

Serotonin Toxicity (also known as Serotonin Syndrome): HYDROMORPH CONTIN can cause Serotonin toxicity, 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 HYDROMORPH CONTIN with certain anti-depressants, migraine medications or muscle relaxants medications.

Serotonin toxicity 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.

Sleep Apnea: Opioids can cause a problem called sleep apnea (stopping breathing from time to time while sleeping). Tell your healthcare professional if you have a history of sleep apnea or if anyone notices that you stop breathing from time to time while sleeping.

Worsened pain: Taking opioids for pain can sometimes have the unintended effect of making your pain feel worse (opioid-induced hyperalgesia) even though your opioid dose has been unchanged or increased. This can also include feeling pain in new places in your body, or feeling pain from something that would not normally hurt, for example, feeling pain from clothing touching your skin. Tell your healthcare professional if you notice a change like this in your pain while you are taking HYDROMORPH CONTIN.

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

Serious Drug Interactions

Taking HYDROMORPH CONTIN with the following medicines can cause serious side effects, including breathing problems that can lead to death:

- alcohol, including prescription and non-prescription medications that contain alcohol. Do NOT drink alcohol while you are taking HYDROMORPH CONTIN. It can lead to:
 - drowsiness,
 - unusually slow or weak breathing,
 - serious side effects or,
 - a fatal overdose.
- Monoamine Oxidase Inhibitors (MAOIs), used to treat depression. Do NOT take HYDROMORPH CONTIN with MAOIs or if you have taken an MAOIs in the last 14 days.

- benzodiazepines, medicines used to help you sleep or that help reduce anxiety (e.g. diazepam, lorazepam, alprazolam).
- antiepileptics, used to treat and prevent seizures (e.g., gabapentin, carbamazepine, phenytoin, oxcarbazepine, phenobarbital).
- drugs used to treat nerve pain (e.g. pregabalin)
- drugs used to prevent and control seizures in the treatment of epilepsy (e.g. gabapentin)
- other sedative drugs which may enhance the drowsiness caused by HYDROMORPH CONTIN.

The following may interact with HYDROMORPH CONTIN:

- alcohol, including prescription and non-prescription medications containing alcohol. **Do not** drink alcohol while taking HYDROMORPH CONTIN. 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 HYDROMORPH CONTIN
- other opioid analgesics, medicines used to treat pain (e.g. butorphanol, nalbuphine, pentazocine, buprenorphine).
- general anesthetics (medicines used during surgery).
- drugs used to treat serious mental or emotional disorders, such as schizophrenia.
- antihistamines, medicines used to treat allergies.
- anti-emetics (for the prevention of vomiting).
- muscle relaxants drugs used to treat muscle spasms and back pain (e.g. baclofen).
- anticoagulants (blood thinners).
- some heart medication (such as beta blockers).
- drugs used to treat migraines (e.g. triptans).
- St. John's Wort.

How to take HYDROMORPH CONTIN:

Take HYDROMORPH CONTIN:

- exactly as prescribed
- every 12 hours

HYDROMORPH CONTIN can be swallowed whole or sprinkled on applesauce or custard.

Swallowed:

- swallow the capsule whole
- take the capsule with a full glass of water
- **do not** cut, break, chew, dissolve or crush the capsule - this can be dangerous and life threatening

Sprinkled:

- measure a tablespoon of warm or cold (4° - 40°C) applesauce or room temperature custard
- open the capsule
- sprinkle contents onto the tablespoon
- ensure the capsule is emptied of all contents
- take the entire tablespoon as soon as possible
- **do not** chew the contents (beads)
- rinse your mouth and swallow the water

- **do not** keep any of the food/medicine mixture for another dose

If you do not remember when you sprinkled the medicine on the applesauce or custard, or which food you sprinkled the medicine on, throw out the food/medicine mixture.

Do not take a single dose greater than 12 mg of HYDROMORPH CONTIN every 12 hours unless you are “opioid tolerant”. Your healthcare professional will tell you when you are “opioid tolerant” to a certain dose of HYDROMORPH CONTIN.

Usual Dose:

Dosage is individualized. Be sure to follow your healthcare professional’s dosing instructions exactly. Do not increase or decrease your dose without consulting your healthcare professional. Taking higher doses can lead to more side effects and greater chance of overdose.

Review your pain regularly with your healthcare professional to determine if you still need HYDROMORPH CONTIN. Be sure to use HYDROMORPH CONTIN only for the condition for which it was prescribed.

Should your pain increase or any other complaint develop as a result of taking HYDROMORPH CONTIN, tell your healthcare professional immediately.

Stopping your Medication:

You should not stop taking HYDROMORPH CONTIN all at once if you have been taking it for more than a few days. Your healthcare professional will monitor and guide you on how to slowly stop taking HYDROMORPH CONTIN. 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 with 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 HYDROMORPH CONTIN.

Refilling your Prescription for HYDROMORPH CONTIN:

A new written prescription is required from your healthcare professional each time you need more HYDROMORPH CONTIN. Therefore, it is important that you contact your healthcare professional before your current supply runs out.

Only obtain prescriptions for this medicine from the healthcare professional in charge of your treatment. Do not seek prescriptions from other healthcare professionals unless you switch to another healthcare professional for your pain management.

Overdose:

If you think you have taken too much HYDROMORPH CONTIN, 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:

It is important that you do not miss any doses. If you miss a dose, take your next dose at your usual time. You should always try to get back on track with your regular dosing schedule (e.g., 8 o'clock in the morning and 8 o'clock in the evening). If you miss several doses in a row, talk to your healthcare professional before restarting your medication.

What are possible side effects from using HYDROMORPH CONTIN?

These are not all the possible side effects you may feel when taking HYDROMORPH CONTIN. If you experience any side effects not listed here, contact your healthcare professional.

Side effects may include:

- confusion
- constipation
- dizziness
- drowsiness
- light-headedness
- nausea, vomiting, or poor appetite
- lack of muscle strength
- sleepiness
- sweating
- low sex drive, impotence (erectile dysfunction), infertility
- itching
- dry mouth
- insomnia
- abdominal pain
- headache
- anxiety
- problems with vision
- weakness, uncoordinated muscle movement

Talk with your healthcare professional or pharmacist about ways to prevent constipation when you start using HYDROMORPH CONTIN.

If nausea and vomiting become troublesome during prolonged therapy with HYDROMORPH CONTIN, talk to your healthcare professional or pharmacist.

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 Toxicity (also known as 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

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 unused or expired HYDROMORPH CONTIN in a secure place to prevent theft, misuse or accidental exposure.**
- Store at room temperature (15° - 25°C). Keep in a dry place.
- **Keep HYDROMORPH CONTIN 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 HYDROMORPH CONTIN, get emergency help right away.**

Disposal:

HYDROMORPH CONTIN 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 HYDROMORPH CONTIN:

- 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://health-products.canada.ca/dpd-bdpp/>); the manufacturer's website <http://www.purdue.ca>, or by calling 1-800-387-4501.

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