

## Patient Medication Information

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

#### **CODEINE CONTIN<sup>®</sup>**

#### **Codeine Controlled Release Tablets**

This patient medication information is written for the person who will be taking **CODEINE CONTIN**. This may be you or a person you are caring for. Read this information carefully. Keep it as you may need to read it again.

This patient medication information is a summary. It will not tell you everything about this medication. If you have more questions about this medication or want more information about **CODEINE CONTIN**, talk to a healthcare professional.

#### **Serious warnings and precautions box**

- Even if you take CODEINE CONTIN as prescribed you are at a 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 healthcare professional.
- When you take CODEINE CONTIN tablets, they must be swallowed whole. Do NOT cut, break, crush, chew, or dissolve the tablet. This can be dangerous and can lead to death or seriously harm you.
- Life-threatening breathing problems can happen while taking CODEINE 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.
- Never give anyone your CODEINE CONTIN. They could die from taking it. If a person has not been prescribed CODEINE CONTIN, taking even one dose can cause a fatal overdose. This is especially true for children.
- If you took CODEINE 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 fever;get immediate medical help for your baby.
- Taking CODEINE 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 CODEINE CONTIN is used for:**

- the management of mild or moderate pain in adults.

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

**How CODEINE CONTIN works:**

CODEINE CONTIN is a painkiller belonging to the class of drugs known as opioids. It relieves pain by acting on specific nerve cells of the spinal cord and brain.

**The ingredients in CODEINE CONTIN are:**

Medicinal ingredients: codeine monohydrate and codeine sulfate trihydrate.

Non-medicinal ingredients: hydroxyethyl cellulose, hydroxypropyl cellulose, hydroxypropyl methylcellulose, lactose, magnesium stearate, polyethylene glycol, stearyl alcohol, talc, and titanium dioxide.

In addition, the tablet strengths listed below contain the following dyes:

- 50 mg: FD&C Blue No. 2 Aluminum Lake.
- 100 mg: FD&C Yellow No. 10 Aluminum Lake, and FD&C Yellow No. 6 Aluminum Lake.
- 150 mg: FD&C Yellow No. 6 Aluminum Lake, and FD&C Red No. 40 Aluminum Lake.
- 200 mg: FD&C Yellow No. 6 Aluminum Lake.

**CODEINE CONTIN comes in the following dosage forms:**

Controlled Release Tablets: 50 mg, 100 mg, 150 mg, and 200 mg of codeine (as codeine monohydrate and codeine sulfate trihydrate).

**Do not use CODEINE CONTIN if:**

- your healthcare professional did not prescribe for you.
- you are allergic to codeine, other opioids, or any of the other ingredients in CODEINE 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 a heart condition called cor pulmonale (right-sided heart failure).
- you have bowel blockage or narrowing of the stomach or intestines.
- you have a condition where the bowel does not work properly (ileus) or you have severe pain in your abdomen (for example from appendicitis or pancreatitis).
- you have increased pressure in your skull or have a head injury.
- you have severe central nervous system (CNS) depression (nervous system slows down).
- you have a history with epilepsy (seizures).
- you suffer from alcoholism or alcohol withdrawal.
- you are taking or have taken within the past 2 weeks a monoamine oxidase inhibitor (MAOI) used to treat depression (such as phenelzine sulfate, tranylcypromine sulfate, moclobemide, or selegiline).
- you are pregnant, or you are in labour or delivery.
- you are breastfeeding.
- you are under 12 years of age.
- you are under 18 years old and are having (or have recently had) your tonsils or adenoids removed because of frequent interruption of breathing during sleep.

- you take certain drugs known as “CYP2D6 metabolizers”. Ask your healthcare professional if you are unsure.

**To help avoid side effects and ensure proper use, talk to your healthcare professional before you take CODEINE 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 kidney, liver, or lung problems.
- have been told you are at risk of having heart problems or seizures.
- have low blood pressure.
- have a sleep disorder which causes pauses in breathing or shallow breathing while sleeping (sleep apnea).
- suffer from chronic or severe constipation.
- have problems with your thyroid, adrenal, or prostate gland.
- have or have had problems with your mood (such as depression or anxiety), hallucinations, or other mental health problems.
- are planning to become pregnant
- are going to have a surgery or operation, or have had a surgery in the last 24 hours.
- have circulatory problems (e.g., body does not get enough oxygen and nutrients to function properly due to lack of blood flow).
- have a history of pancreas or gall bladder problems.
- have a condition that causes weakness or frailty.
- have gastrointestinal (GI) problems.
- difficulty urinating.
- plan on drinking alcohol. Drinking alcohol while taking CODEINE CONTIN may cause dangerous side effects, including death. Do NOT drink alcohol while taking CODEINE CONTIN.
- plan to breastfeed.
- have been told that you are “opioid tolerant”.
- know that you metabolize codeine faster than the general population. This can lead to accidental overdose.
- are 65 years of age or older.
- have diabetes.

Ask your healthcare professional if you are unsure about these and any health conditions or problems you may have.

**Other warnings you should know about:**

Taking CODEINE CONTIN can cause the following serious side effects:

- **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 CODEINE CONTIN.

- **Serotonin toxicity (also known as serotonin syndrome):** CODEINE 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 toxicity if you take CODEINE CONTIN with certain anti-depressants or migraine 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.
- **Sleep apnea:** Opioids can cause a problem called sleep apnea (pauses in breathing or shallow breathing 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 CODEINE CONTIN.

See the **Serious side effects and what to do about them** table below for more information on these and other serious side effects.

### ***Drug addiction, dependence, and tolerance***

Like any opioid, if you use CODEINE CONTIN for a long time, it may cause mental and physical dependence. Codeine also has the potential to cause addiction. There are important differences between physical dependence and addiction. If you use opioids for a long time, you may develop tolerance. This means that you may need higher doses of CODEINE CONTIN to feel 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 CODEINE 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 CODEINE CONTIN while pregnant, nursing, during labour or delivery. Opioids can be transferred to your baby through breast milk, or while still in the womb. CODEINE CONTIN can then cause life-threatening breathing problems in your unborn baby or nursing infant. If you become pregnant while taking CODEINE CONTIN, tell your healthcare professional right away.

If you are pregnant and are taking CODEINE 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 healthcare professional will monitor and guide you on how to slowly stop taking CODEINE 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 CODEINE CONTIN. CODEINE CONTIN can cause:

- drowsiness,
- dizziness, or
- light-headedness.

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

### ***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.

### ***Testing and check-ups***

Your healthcare professional will regularly monitor your health. This includes monitoring for signs of:

- misuse and abuse;
- sleep apnea (a sleep disorder which causes pauses in breathing or shallow breathing while sleeping);
- respiratory depression and sedation (e.g., slow, shallow, or weak breathing).

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

### **Serious drug interactions:**

Serious drug interactions with CODEINE CONTIN include:

- benzodiazepines used to help you sleep or that help reduce anxiety.
- other central nervous system (CNS) depressants used to slow down the nervous system. These can include:
  - other opioids and mixed opioid agonists/antagonists used to relieve pain (e.g., pentazocine, nalbuphine, butorphanol, and buprenorphine);
  - hypnotics used to help with sleeping;
  - antidepressants used for depression and mood disorders (e.g., tricyclic antidepressants; serotonin norepinephrine re-uptake inhibitors (SNRIs); and selective serotonin re-uptake inhibitors (SSRIs) such as St. John's Wort);
  - anxiolytics, tranquilizers, and phenothiazines used to treat mental or emotional disorders;
  - muscle relaxants used to treat muscle spasms and back pain (e.g., baclofen);
  - general anaesthetics used during surgery;
  - antipsychotics and neuroleptics used to treat mental health disorders;
  - antihistamines used to treat allergies;
  - antiemetics used to prevent nausea or vomiting;
  - sedatives which may enhance the drowsiness;
  - pregabalin, used to treat nerve pain;
  - gabapentin, used to prevent and control seizures in the treatment of epilepsy
  - beta blockers used to lower blood pressure;

- alcohol. This includes prescription and non-prescription medications that contain alcohol. Do NOT drink alcohol while you are taking CODEINE 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 CODEINE CONTIN with MAOIs or if you have taken MAOI's in the last 14 days.

**The following may also interact with CODEINE CONTIN:**

- anticoagulants used to thin the blood and prevent blood clots (e.g., warfarin).

**How to take CODEINE CONTIN:**

- Take CODEINE CONTIN exactly as prescribed by your healthcare professional. Check with your healthcare professional if you are unsure.
- CODEINE CONTIN must be taken orally, by mouth, with a full glass of water. Do NOT take CODEINE CONTIN via any other route as this can cause serious harm, including death.
- **Swallow tablets whole. Do NOT cut, break, crush, chew, or dissolve the tablet. This can be dangerous and can lead to death or seriously harm you.**
- For three of the four dose strengths (100 mg, 150 mg and 200 mg), the tablet is scored and may be broken in half. Do NOT cut, break, crush, chew or dissolve the half tablet.
- CODEINE CONTIN can be taken with or without food.
- Review your pain regularly with your healthcare professional to determine if you still need CODEINE CONTIN. Be sure to use CODEINE CONTIN only for the condition for which it was prescribed.

**Usual dose:**

Your dose is tailored/personalized just for you. Be sure to exactly follow your healthcare professional's dosing instructions. Do not increase or decrease your dose without consulting your healthcare professional. Taking higher dose can lead to more side effects and a greater chance of overdose.

***Stopping your Medication:***

If you have been taking CODEINE CONTIN for more than a few days, you should not stop taking it all of a sudden. Your healthcare professional will monitor and guide you on how to slowly stop taking CODEINE 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 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 CODEINE CONTIN.

### **Refilling your prescription for CODEINE CONTIN**

A new written prescription is required from your healthcare professional each time you need more CODEINE 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:**

Signs of overdose with CODEINE CONTIN may include:

- unusually slow or weak breathing,
- dizziness,
- confusion,
- extreme drowsiness,
- hypoglycemia (low blood sugar).

If you think you, or a person you are caring for, have taken too much CODEINE CONTIN, contact a healthcare professional, hospital emergency department, regional poison control centre, or Health Canada's toll-free number, 1-844 POISON-X (1-844-764-7669) immediately, even if there are no signs or symptoms.

### **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 healthcare professional before restarting your medication.

### **Possible side effects from using CODEINE CONTIN:**

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

Side effects with CODEINE CONTIN may include:

- confusion
- drowsiness
- insomnia
- dizziness
- fainting
- nausea, vomiting, or a poor appetite
- dry mouth
- headache
- problems with vision

- weakness, uncoordinated muscle movement
- itching
- light headedness
- sweating
- low sex drive, impotence (erectile dysfunction), infertility
- constipation. Talk with your healthcare professional about ways to prevent constipation when you start using CODEINE CONTIN.

### Serious side effects and what to do about them

Frequency/Side Effect/Symptom	Talk to your healthcare professional		Stop taking the drug and get immediate medical help
	Only if severe	In all cases	
<b>Rare</b>			
<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, or nausea.			√
<b>Fast, slow, or irregular heartbeat:</b> heart palpitations.		√	
<b>Hypotension</b> (low blood pressure): dizziness, fainting, or light-headedness.	√		
<b>Overdose:</b> hallucinations, confusion, inability to walk normally, slow or weak breathing, extreme sleepiness, sedation, or dizziness, floppy muscles/low muscle tone, or cold and clammy skin.			√
<b>Respiratory depression:</b> slow, shallow or weak breathing.			√
<b>Serotonin toxicity (also known as serotonin syndrome):</b> a reaction which may cause feelings of agitation or restlessness, flushing, muscle twitching, involuntary eye movements, heavy sweating, high body temperature (>38°C), or rigid muscles.			√
<b>Withdrawal:</b> nausea, vomiting, diarrhea, anxiety, shivering, cold and clammy skin, body aches, loss of appetite, or sweating.		√	
<b>Unknown</b>			
<b>Disorder of the adrenal gland:</b> nausea, vomiting, anorexia, fatigue, weakness, dizziness, or low blood pressure.			√
<b>Hypoglycemia</b> (decreased blood sugar): dizziness, lack of energy, drowsiness, headache, trembling, or sweating.			√
<b>Sleep apnea:</b> stop breathing for short periods during your normal nightly sleep.		√	



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://canada.ca/drug-device-reporting>) for information on how to report online, by mail or by fax; or
- Calling toll-free at 1-866-234-2345.

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

### **Storage:**

- Store CODEINE CONTIN at room temperature (15°C to 30°C). Keep in a dry place.
- Keep unused or expired CODEINE CONTIN in a secure place to prevent theft, misuse or accidental exposure. It should be kept 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 CODEINE CONTIN, get emergency help right away.
- CODEINE 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 CODEINE CONTIN:**

- Talk to your healthcare professional.
- Find the full Product Monograph that is prepared for healthcare professionals and includes the Patient Medication Information by visiting the Health Canada Drug Product Database website (<https://www.canada.ca/en/health-canada/services/drugs-health-products/drug-products/drug-product-database.html>); the manufacturer's website ([www.purdue.ca](http://www.purdue.ca)), or by calling 1-800-387-4501.

This leaflet was prepared by Purdue Pharma.

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