

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

N[®]CODEINE CONTIN[®]
Codeine Controlled Release Tablets

Read this carefully before you start taking CODEINE 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 CODEINE CONTIN.

Serious Warnings and Precautions

- 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 prescriber (e.g., doctor).
- 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 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 feverSeek 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 is CODEINE CONTIN used for?

- CODEINE CONTIN is a medicine used to manage your pain

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

How does CODEINE CONTIN work?

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

What are the ingredients in CODEINE CONTIN?

Medicinal ingredients: codeine

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 - D&C Yellow No. 10 Aluminum Lake, FD&C Yellow No. 6 Aluminum Lake

150 mg - FD&C Yellow No. 6 Aluminum Lake, FD&C Red No. 40 Aluminum Lake

200 mg - FD&C Yellow No. 6 Aluminum Lake

CODEINE CONTIN comes in the following dosage forms:

CODEINE CONTIN Controlled Release Tablets 50 mg, 100 mg, 150 mg and 200 mg.

Do not use CODEINE CONTIN if:

- your doctor 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 condition where the small bowel does not work properly (paralytic ileus) 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 going to have, or recently had, a planned surgery
- you are taking or have taken within the past 2 weeks a monoamine oxidase inhibitor (such as phenelzine sulfate, tranylcypromine sulfate, moclobemide or selegiline)
- you had surgery within the last 12-24 hours or are going to have a planned surgery
- you are pregnant or planning to become pregnant, or in labour
- you are breastfeeding. The use of codeine-containing products while breast-feeding may harm your baby. If you breastfeed and take CODEINE CONTIN seek immediate medical care for your baby if they are overly drowsy, sedated, have difficulty breast-feeding, have breathing difficulties, and are floppy (have decreased muscle tone). This is very serious for the baby and can lead to death. Tell the baby’s doctor that you are breastfeeding and took CODEINE CONTIN.
- 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

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 severe kidney, liver, lung disease
- have heart disease
- have low blood pressure
- have a history of sleep apnea
- 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 planning to become pregnant

Other warnings you should know about:

Some people metabolize codeine at a much faster rate than the general population, which may lead to accidental overdose, if this should happen to you, seek help immediately (see Overdose, for symptoms of overdose and what to do if it happens). If you know that you metabolize codeine rapidly, tell your doctor BEFORE starting this medication.

CODEINE CONTIN is not recommended for anyone who has or is at risk for breathing problems such as:

- lung infections, or respiratory conditions
- neuromuscular disorders
- severe heart problems
- recent multiple traumas or extensive surgical procedures

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 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.

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.

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 CODEINE CONTIN.

Serotonin Syndrome

CODEINE CONTIN 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 CODEINE CONTIN 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.

Sleep apnea

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

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 CODEINE CONTIN:

- 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
- other sedative drugs which may enhance the drowsiness caused by CODEINE CONTIN
- other opioid analgesics (for pain)
- general anesthetics (used during surgery)
- drugs used to help you sleep or that help reduce anxiety (benzodiazepines)
- antidepressants (for depression and mood disorders). **Do not** take CODEINE CONTIN with monoamine oxidase (MAO) inhibitors or if you have taken MAO inhibitors in the last 14 days before treatment with CODEINE CONTIN
- drugs used to treat serious mental or emotional disorders, such as schizophrenia
- antihistamines (for allergies)
- anti-emetics (for the prevention of vomiting)

- drugs used to treat muscle spasms and back pain
- some heart medications (such as beta blockers)
- anticoagulants (blood thinners)
- drugs used to treat migraines (e.g. triptans)
- St. John's Wort

How to take CODEINE CONTIN:

Take CODEINE CONTIN tablets every 12 hours with or without food with a full glass of water

Swallow 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, 150mg and 200mg), the tablet is scored and may be broken in half. Do not cut, break, crush, chew or dissolve the half tablet.

Usual 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. Taking higher dose 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 CODEINE CONTIN. Be sure to use CODEINE CONTIN only for the condition for which it was prescribed.

If your pain increases or you develop any side effect as a result of taking CODEINE CONTIN, tell your doctor immediately.

Stopping your Medication:

You should not stop taking CODEINE CONTIN all at once if you have been taking it for more than a few days.

Your doctor 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 doctor each time you need more CODEINE CONTIN. Therefore, it is important that you contact your doctor before your current supply runs out.

Only obtain prescriptions for this medicine 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 CODEINE 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:

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 CODEINE CONTIN?

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

Side effects 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
- constipation
- low sex drive, impotence (erectile dysfunction), infertility

Talk with your doctor or pharmacist about ways to prevent constipation when you start using CODEINE CONTIN.

| 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

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/drug.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 CODEINE CONTIN in a secure place to prevent theft, misuse or accidental exposure.
- Store at room temperature (15°C - 30°C). Keep in a dry place.
- Keep CODEINE 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 CODEINE CONTIN, get emergency help right away.

Disposal:

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 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.purdue.ca, or by calling 1-800-387-4501.

This leaflet was prepared by Purdue Pharma

Last Revised: August 7, 2020

CODEINE CONTIN® is a registered trademark of Purdue Pharma.