READ THIS FOR SAFE AND EFFECTIVE USE OF YOUR MEDICINE

PATIENT MEDICATION INFORMATION

TYLENOL® with Codeine No. 4
acetaminophen and codeine phosphate tablets

Read this carefully before you start taking TYLENOL® with Codeine No. 4 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 TYLENOL® with Codeine No. 4.

Serious Warnings and Precautions

- Even if you take TYLENOL® with Codeine No. 4 as prescribed you are at a risk for opioid addiction, abuse and misuse. This can lead to overdose and death.

  When you take TYLENOL® with Codeine No. 4 it 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.

- You may get life-threatening breathing problems while taking TYLENOL® with Codeine No. 4. This is less likely to happen if you take it as prescribed by your doctor.

- You should never give anyone your TYLENOL® with Codeine No. 4. They could die from taking it. If a person has not been prescribed TYLENOL® with Codeine No. 4, taking even one dose can cause a fatal overdose. This is especially true for children.

- If you took TYLENOL® with Codeine No. 4 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:
  o has changes in their breathing (such as weak, difficult or fast breathing)
  o is unusually difficult to comfort
  o has tremors (shakiness)
  o has increased stools, sneezing, yawning, vomiting, or fever
Seek immediate medical help for your baby.

- Taking TYLENOL® with Codeine No. 4 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 TYLENOL® with Codeine No. 4 used for?
TYLENOL® with Codeine No. 4 is used for the short-term relief of moderate to severe pain.
TYLENOL® with Codeine No. 4 should not be taken for pain for more than 5 days, unless directed by your healthcare professional.

**How does TYLENOL® with Codeine No. 4 work?**
TYLENOL® with Codeine No. 4 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.

**What are the ingredients in TYLENOL® with Codeine No. 4?**
Medicinal ingredients: acetaminophen and codeine phosphate.
Non-medicinal ingredients: cellulose, cornstarch, magnesium stearate, sodium lauryl sulfate, sodium starch glycolate and talc.

**TYLENOL® with Codeine No. 4 comes in the following dosage form:**
300 mg acetaminophen and 60 mg codeine phosphate tablets.

**Do not use TYLENOL® with Codeine No. 4 if you:**
- are allergic to acetaminophen, codeine or any of the other ingredients in TYLENOL® with Codeine No. 4
- can control your pain by the occasional use of other pain medications. This includes those available without a prescription
- have severe asthma, trouble breathing or other breathing problems
- have any heart problems
- have bowel blockage or narrowing of the stomach or intestines
- have severe pain in your abdomen
- have a head injury
- are at risk for seizures
- suffer from alcoholism
- are taking or have taken within the past 2 weeks a Monoamine Oxidase inhibitor (MAOi) (such as phenelzine sulphate, tranylcypromine sulphate, moclobemide or selegiline)
- are going to have a planned surgery
- are in labour
- are breastfeeding
- are less than 18 years old and are having (or have recently had) your tonsils or adenoids removed because of frequent interruption of breathing during sleep
- have serious liver or kidney problems
- have slow or shallow breathing, elevated carbon dioxide levels in the blood or a condition called “cor pulmonale” in which part of the heart is enlarged or does not work correctly due to high blood pressure in the lungs
- convert codeine into its active metabolite more rapidly and completely than other people (see *Ultra-Rapid Metabolizers of Codeine*)
- are less than 12 years old

To help avoid side effects and ensure proper use, talk to your healthcare professional.
before you take TYLENOL® with Codeine No. 4. 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 liver or kidney problems
- have low blood pressure
- have or had depression
- suffer from chronic or severe constipation
- have problems with your thyroid, adrenal or prostate gland
- have difficulty urinating
- have, or had in the past hallucinations or other severe mental problems
- develop allergic reactions such as wheezing, rash or itching
- feel sedated or drowsy, are confused or have slow, shallow breathing
- have redness or swelling present in an area of pain, if symptoms do not improve or if they worsen, or if new symptoms such as high fever, rash, itching, wheezing or persistent headache occur
- have pain that lasts more than 5 days or for fever more than 3 days
- are less than 18 years and are having breathing problems
- have difficulty breathing, asthma or chronic lung disease
- are pregnant or are planning to get pregnant
- suffer from migraines
- are elderly or debilitated
- take tranquilizers, sedatives, sedating antihistamines or other depressants, salicylates, other pain and fever relief medications or nonsteroidal anti-inflammatory drugs (NSAIDs)

Other warnings you should know about:

Driving and using machines: Before you do tasks which may require special attention, you should wait until you know how you react to TYLENOL® with Codeine No. 4. TYLENOL® with Codeine No. 4 can cause:
- drowsiness
- dizziness or
- lightheadedness

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

Ultra-Rapid Metabolizers of Codeine:
Some individuals process codeine more rapidly and completely than others. This rapid processing in the body results in higher than expected drug levels. Even at the recommended doses, people whose bodies are ultra-rapid processors may have life-threatening or fatal effects on their breathing or experience overdose symptoms such as extreme sleepiness, confusion, or shallow breathing.

Drug Abuse and Dependence:
Codeine can produce drug dependence and has the potential for being abused. Tolerance, psychological and physical dependence may develop over time with repeated use of TYLENOL®
with Codeine No. 4. Your healthcare professional should prescribe and administer TYLENOL® with Codeine No. 4 with the same degree of caution appropriate to the use of other oral opioid medications. Using these products for a prolonged period of time is not recommended.

**Serious skin reactions (Stevens - Johnson Syndrome, Toxic Epidermal Necrolysis, Hypersensitivity Syndrome):**
Acetaminophen can cause serious skin reactions that can spread to your mouth, lips, face, hands, trunk, arms and legs. This condition is life-threatening. Stop taking TYLENOL® with Codeine No. 4 and contact your healthcare professional immediately if you develop a rash during treatment (see table of **Serious side effects and what to do about them**, below).

**Liver injury:**
Taking acetaminophen in doses higher than recommended may result in liver injury, including the risk of severe liver disease and death. Do not exceed the maximum recommended daily dose of acetaminophen including all routes of administration (intravenous, oral and rectal) and all products containing acetaminophen (oral solutions/drops, syrup, pills, capsules, suppositories etc.).

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 TYLENOL® with Codeine No. 4:**

- Alcohol. This includes prescription and non-prescription medications that contain alcohol. **Do not** drink alcohol while you are taking TYLENOL® with Codeine No. 4. It can lead to:
  - drowsiness
  - unusually slow or weak breathing
  - serious side effects or
  - a fatal overdose
- 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 TYLENOL® with Codeine No. 4 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)
- drugs used to treat migraines (e.g., triptans)
- antihistamines (drugs used to treat allergies)
- anti-emetics (drugs used for the prevention of vomiting)
- drugs used to treat muscle spasms and back pain
- warfarin (such as COUMADIN®) and other anticoagulants (used for prevention or treatment of blood clots)
- anti-retroviral drugs (used to treat viral infections)
- anti-fungal drugs (used to treat fungal infections)
• antibiotic drugs (used to treat bacterial infections)
• some heart medication (such as beta blockers)

How to take TYLENOL® with Codeine No. 4:

Use the smallest effective dose for the shortest period of time. Only take this medication when you need it, and never more often than every 4 to 6 hours.

Do not take with other drugs containing acetaminophen.

Do not exceed the maximum recommended dose. Overdose may result in severe or possibly fatal liver damage.

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.

Usual Adult Starting Dose:

TYLENOL® with Codeine No. 4 tablets:  
Take 1 tablet every 4-6 hours as required, not to exceed 6 tablets in 24 hours.

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.

Review your pain regularly with your doctor to determine if you still need TYLENOL® with Codeine No. 4. Be sure to use TYLENOL® with Codeine No. 4 only for the condition for which it was prescribed.

If your pain increases or you develop any side effect as a result of taking TYLENOL® with Codeine No. 4, tell your doctor immediately.

Stopping your Medication

If you have been taking TYLENOL® with Codeine No. 4 for more than a few days you should not stop taking it all of a sudden. You should check with your doctor for directions on how to slowly stop taking it. You should do it slowly to avoid uncomfortable symptoms such as having:

• body aches
• diarrhea
• gooseflesh
• 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
• an unexplained fever
• weakness
• yawning

Refilling your Prescription for TYLENOL® with Codeine No. 4:

A new written prescription is required from your doctor each time you need more TYLENOL® with Codeine No. 4. Therefore, it is important that you contact your doctor before your current supply runs out.

Overdose:

Overdose may result in severe or possibly fatal liver damage.

If you think you have taken too much TYLENOL® with Codeine No. 4, 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 succession, talk to your doctor before restarting your medication.

What are possible side effects from using TYLENOL® with Codeine No. 4?

These are not all the possible side effects you may feel when taking TYLENOL® with Codeine No. 4. 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
- Low sex drive, impotence (erectile dysfunction), infertility

Talk with your doctor or pharmacist about ways to prevent constipation when you start using TYLENOL® with Codeine No. 4.

<table>
<thead>
<tr>
<th>Symptom / effect</th>
<th>Talk to your healthcare professional</th>
<th>Stop taking drug and get immediate medical help</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Only if severe</td>
<td>In all cases</td>
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<tr>
<td><strong>RARE</strong></td>
<td></td>
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<tr>
<td><strong>Overdose</strong>: hallucinations, confusion, inability to walk normally, slow or weak breathing, extreme sleepiness, sedation, or dizziness, floppy muscles/low muscle tone cold and clammy skin.</td>
<td></td>
<td>✓</td>
</tr>
<tr>
<td><strong>Respiratory Depression</strong>: Slow, shallow or weak breathing.</td>
<td></td>
<td>✓</td>
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<tr>
<td><strong>Allergic Reaction</strong>: rash, hives, swelling of the face, lips, tongue, or throat, difficulty swallowing or breathing.</td>
<td></td>
<td>✓</td>
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<tr>
<td><strong>Bowel Blockage (impaction)</strong>: abdominal pain, severe constipation, nausea</td>
<td></td>
<td>✓</td>
</tr>
<tr>
<td><strong>Withdrawal</strong>: nausea, vomiting, diarrhea, anxiety, shivering, cold and clammy skin, body aches,</td>
<td></td>
<td>✓</td>
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<tr>
<td>Symptom / Condition</td>
<td>Description</td>
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<tr>
<td>loss of appetite, sweating.</td>
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<tr>
<td><strong>Fast, Slow or Irregular Heartbeat:</strong></td>
<td>heart palpitations.</td>
<td>✓</td>
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<tr>
<td><strong>Low Blood Pressure:</strong> dizziness, fainting, light-headedness.</td>
<td></td>
<td>✓</td>
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<tr>
<td><strong>Serotonin Syndrome:</strong> agitation or restlessness, loss of muscle control or muscle twitching, tremor, diarrhea</td>
<td></td>
<td>✓</td>
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<tr>
<td><strong>Serious Skin Reactions (Stevens - Johnson Syndrome, Toxic Epidermal Necrolysis, Hypersensitivity Syndrome):</strong></td>
<td>any combination of itchy skin rash, redness, blistering and peeling of the skin and/or of the lips, eyes, mouth, nasal passages or genitals, accompanied by fever, chills, headache, cough, body aches or joint pain, yellowing of the skin or eyes, dark urine.</td>
<td>✓</td>
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<tr>
<td><strong>VERY RARE</strong></td>
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<tr>
<td><strong>Liver Injury:</strong> yellowing of the skin or eyes, dark urine, abdominal pain, nausea, vomiting, loss of appetite.</td>
<td></td>
<td>✓</td>
</tr>
<tr>
<td>Redness or swelling in the area of pain, symptoms that do not improve, or if new symptoms appear such as fever, rash, itching, wheezing or persistent headache.</td>
<td></td>
<td>✓</td>
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</tbody>
</table>

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® (www.healthcanada.gc.ca/medeffect);
- 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 0701E
            Ottawa, ON
            K1A 0K9
            Postage paid labels and the Consumer Side Effect Reporting Form are available

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 bottle tightly closed. Store at 15-30ºC. Protect from light.

Keep unused or expired TYLENOL® with Codeine No. 4 in a secure place to prevent theft, misuse or accidental exposure.

Keep TYLENOL® with Codeine No. 4 out of sight and reach of children and pets.

Disposal:

TYLENOL® with Codeine No. 4 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 TYLENOL® with Codeine No. 4:

- Talk to your healthcare professional
- For questions or concerns contact the manufacturer, Janssen Inc., at www.janssen.com/canada.
- Find the full product monograph that is prepared for healthcare professionals and includes this Patient Medication Information by visiting the Health Canada website (www.healthcanada.gc.ca); the manufacturer’s website (www.janssen.com/canada), or by calling 1-800-567-3331 or 1-800-387-8781.

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