

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

### PATIENT MEDICATION INFORMATION

#### **<sup>N</sup>TYLENOL<sup>®</sup> with Codeine No. 4 acetaminophen and codeine phosphate tablets**

Read this carefully before you start taking **TYLENOL<sup>®</sup> 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<sup>®</sup> with Codeine No. 4**.

#### **Serious Warnings and Precautions**

- **Even if you take **TYLENOL<sup>®</sup> 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<sup>®</sup> 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<sup>®</sup> with Codeine No. 4**. 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 **TYLENOL<sup>®</sup> with Codeine No. 4**. They could die from taking it. If a person has not been prescribed **TYLENOL<sup>®</sup> with Codeine No. 4**, taking even one dose can cause a fatal overdose. This is especially true for children.**
- **If you took **TYLENOL<sup>®</sup> 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:**
  - **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 **TYLENOL<sup>®</sup> 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<sup>®</sup> with Codeine No. 4** used for?**

**TYLENOL<sup>®</sup> with Codeine No. 4** is used for the short-term relief of moderate to severe pain.

TYLENOL<sup>®</sup> with Codeine No. 4 should not be taken for pain for more than 5 days, or fever for more than 3 days, unless directed by your healthcare professional.

**How does TYLENOL<sup>®</sup> with Codeine No. 4 work?**

TYLENOL<sup>®</sup> 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<sup>®</sup> 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<sup>®</sup> with Codeine No. 4 comes in the following dosage form:**

300 mg acetaminophen and 60 mg codeine phosphate tablets.

**Do not use TYLENOL<sup>®</sup> with Codeine No. 4 if:**

- your doctor did not prescribe it for you
- you are allergic to acetaminophen, codeine or any of the other ingredients in TYLENOL<sup>®</sup> with Codeine No. 4
- 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
- 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 Monoamine Oxidase inhibitor (MAOi) (such as phenelzine sulphate, tranylcypromine sulphate, moclobemide or selegiline)
- you are going to have or recently had, a planned surgery
- you are in labour
- you are breastfeeding
- you 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
- you have serious liver or kidney problems
- you 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
- you convert codeine into its active metabolite more rapidly and completely than other people (see *Ultra-Rapid Metabolizers of Codeine*)
- you 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 severe kidney, liver, or lung 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 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)
- take, or plan to take a serotonergic drug, or are not sure whether you are taking a serotonergic drug (e.g. anti-depressants, migraine medications)

**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 TYLENOL® with Codeine No. 4 while nursing, during labour or delivery. Opioids can be transferred to your baby through breast milk or while still in the womb. TYLENOL® with Codeine No. 4 can then cause life-threatening breathing problems in your unborn baby or nursing infant.

If you are pregnant, your doctor will determine if the benefits of using TYLENOL® with Codeine No. 4 outweigh the risks to your unborn baby. In addition, if you are pregnant and are taking this medication, it is important that you don't stop taking it all of a sudden. Your doctor will monitor and guide you on how to slowly stop taking TYLENOL® with Codeine No. 4. 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 TYLENOL<sup>®</sup> with Codeine No. 4. TYLENOL<sup>®</sup> 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.

**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 TYLENOL<sup>®</sup> with Codeine No. 4.

**Serotonin Syndrome:** TYLENOL<sup>®</sup> with Codeine No. 4 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 TYLENOL<sup>®</sup> with Codeine No. 4 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.

**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<sup>®</sup> with Codeine No. 4. Your healthcare professional should prescribe and administer TYLENOL<sup>®</sup> 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<sup>®</sup> 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<sup>®</sup> with Codeine No. 4:**

- Alcohol. This includes prescription and non-prescription medications that contain alcohol. **Do not** drink alcohol while you are taking TYLENOL<sup>®</sup> with Codeine No. 4. 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 TYLENOL<sup>®</sup> with Codeine No. 4
- 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<sup>®</sup> 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<sup>®</sup>) 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)
- St. John's Wort

#### **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:**

Your doctor will prescribe the lowest dose that works to control your pain or fever. It is recommended that you take TYLENOL® with Codeine No. 4 for a maximum of 3 days for fever and a maximum of 5 days for pain, unless otherwise directed by your healthcare professional. If you need to take TYLENOL® with Codeine No. 4 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.

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. Your doctor will monitor and guide you on how to slowly stop

taking **TYLENOL<sup>®</sup>** with Codeine No. 4. 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 **TYLENOL<sup>®</sup>** with Codeine No. 4.

#### **Refilling your Prescription for **TYLENOL<sup>®</sup>** with Codeine No. 4:**

A new written prescription is required from your doctor each time you need more **TYLENOL<sup>®</sup>** with Codeine No. 4. 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:**

Overdose may result in **severe or possibly fatal liver damage.**

If you think you have taken too much **TYLENOL<sup>®</sup>** 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 a row, 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.

<b>Serious side effects and what to do about them</b>			
Symptom / effect	Talk to your healthcare professional		Stop taking drug and get immediate medical help
	Only if severe	In all cases	
<b>RARE</b>			
<b>Overdose:</b> hallucinations, confusion, inability to walk normally, slow or weak breathing, extreme sleepiness, sedation, or			✓

dizziness, floppy muscles/low muscle tone, cold and clammy skin.			
<b>Respiratory Depression:</b> Slow, shallow or weak breathing.			✓
<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, nausea			✓
<b>Withdrawal:</b> nausea, vomiting, diarrhea, anxiety, shivering, cold and clammy skin, body aches, loss of appetite, sweating.		✓	
<b>Fast, Slow or Irregular Heartbeat:</b> heart palpitations.		✓	
<b>Low Blood Pressure:</b> dizziness, fainting, light-headedness.	✓		
<b>Serotonin Syndrome:</b> agitation or restlessness, loss of muscle control or muscle twitching, tremor, diarrhea			✓
<b>Serious Skin Reactions (Stevens - Johnson Syndrome, Toxic Epidermal Necrolysis, Hypersensitivity Syndrome):</b> 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.			✓
<b>VERY RARE</b>			
<b>Liver Injury:</b> yellowing of the skin or eyes, dark urine, abdominal pain, nausea, vomiting, loss of appetite.		✓	
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.		✓	

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<sup>®</sup> (<https://www.canada.ca/en/health-canada/services/drugs-health-products/medeffect-canada/adverse-reaction-reporting.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<sup>®</sup> (<https://www.canada.ca/en/health-canada/services/drugs-health-products/medeffect-canada/adverse-reaction-reporting.html>).

*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 TYLENOL<sup>®</sup> with Codeine No. 4 in a secure place to prevent theft, misuse or accidental exposure.**
- Keep bottle tightly closed. Store at 15-30°C. Protect from light.
- **Keep TYLENOL<sup>®</sup> with Codeine No. 4 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 TYLENOL<sup>®</sup> with Codeine No. 4, get emergency help right away.**

### **Disposal:**

**TYLENOL<sup>®</sup> 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<sup>®</sup> with Codeine No. 4:**

- Talk to your healthcare professional
- For questions or concerns contact the manufacturer, Janssen Inc., at [www.janssen.com/canada](http://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 (<https://www.canada.ca/en/health-canada/services/drugs-health-products/drug-products/drug-product-database.html>); the manufacturer's website ([www.janssen.com/canada](http://www.janssen.com/canada)), or by calling 1-800-567-3331 or 1-800-387-8781.

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