



ZERO
PREVENTABLE HARM
FROM MEDICATIONS

Canadian Initiatives to Support Safe Use of Acetaminophen (Paracetamol)

EMR Countries Workshop
Rabat, Morocco
Sylvia Hyland October 2019





ENABLE

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ISMP Canada is an independent not-for-profit organization dedicated to reducing preventable harm from medications

Our Vision: Zero preventable harm from medications

Our Mission: to identify risks in medication use systems, recommend optimal system safeguards, and advocate for safe medication practices





Outline

- **Canadian Context**
- **Magnitude of Problem**
- **Risk-Minimization Strategies**
- **Finding the Balance in the midst of an Opioid Crisis**



Canadian Context

- **4500 Canadians hospitalized annually for overdose (2015)**
 - 6% experience liver injury
- **Most overdoses are intentional; 20% are unintentional**
- **The proportion of cases of injury due to unintentional overdose rose from 27% (2006) to 45% (2011)**
- **There are 500 Acetaminophen containing products marketed in Canada**
 - 350 non-prescription products

From Health Canada Summary Safety Review (2015) and Acetaminophen Special Project (2014) cited in: ISMP Canada Safety Bulletin, 2017, Acetaminophen: Preventing Harm through Safe Use. Available from: <https://www.ismp-canada.org/download/safetyBulletins/2017/ISMPCSB2017-04-Acetaminophen.pdf>



Unintentional Overdoses

Possible causes:

- **Belief that non-prescription medications cannot cause harm**
- **Lack of awareness of maximum daily dose**
- **Taking more than one product containing acetaminophen (paracetamol)**
- **Confusion caused by umbrella names**
- **Pediatric dose calculation/measurement errors**

ISMP Canada Safety Bulletin, 2017, Acetaminophen: Preventing Harm through Safe Use. Available from: <https://www.ismp-canada.org/download/safetyBulletins/2017/ISMPCSB2017-04-Acetaminophen.pdf>



Canadian Context cont'd

- **Most liver injuries are caused by doses higher than 4 g per day**
- **In the U.S. manufacturers have voluntarily reduced the labelled daily maximum dose for adults from 4 g to 3g.**
- **The manufacturers have not implemented this labelling change in Canada**

ISMP Canada Safety Bulletin, 2017, Acetaminophen: Preventing Harm through Safe Use. Available from: <https://www.ismp-canada.org/download/safetyBulletins/2017/ISMPCSB2017-04-Acetaminophen.pdf>



Coroner's Office - Public Warning

North

3 deaths in Iqaluit related to prescription Tylenol overdose



'People are assuming that because it's available over the counter it's safe to take at any dose'

CBC News · Posted: Nov 06, 2014 7:05 AM CT | Last Updated: November 7, 2014



Padma Suramala, Nunavut's chief coroner, says lethal amounts of Tylenol are available over the counter. (Vincent Desrosiers/CBC)

Nunavut's coroner's office has issued a public warning about the dangers of Tylenol combined with alcohol after three deaths in Iqaluit — a city of about 7,000 people — in the past eight months.

The deaths include a 45-year-old woman who died in March from Tylenol toxicity in Iqaluit.

The next month, a 71-year-old elder died at the Qikiqtani General Hospital due to Tylenol toxicity and liver failure.

Then this month, a 45-year-old man died due to Tylenol overdose with liver and kidney failure.

2014

- Nunavut's Coroner's Office issued a public warning
- 3 deaths due to acetaminophen toxicity
- All 3 individuals had prescriptions for acetaminophen

Available from: <https://www.cbc.ca/news/canada/north/3-deaths-in-igaluit-related-to-prescription-tylenol-overdose-1.2825716> and <https://www.cbc.ca/news/canada/kitchener-waterloo/improved-labelling-coming-for-over-the-counter-and-prescription-drugs-1.3665135>



Coroner Report - Increased Awareness

WORLD The dark side of acetaminophen

By Jennifer Yang Global health reporter
Robert Cribb Foreign
Fri., Feb. 21, 2014 | 19 min. read



2014

Coroner investigating the case of 19-year old Ashley Campbell classified the acetaminophen overdose death as accidental

Ashley's father advocated for greater awareness:

"As a father I thought about pot, I thought about booze...all the things a dad thinks about with a daughter." "I did not think about acetaminophen."

There was a call for stronger warnings on labels

Available from: https://www.thestar.com/news/world/2014/02/21/the_dark_side_of_acetaminophen.html



ISMP Canada Letter

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READERS' LETTERS

Drug 'umbrella names' confuse users

Tues., March 4, 2014 | 2 min. read

Re: The dark side of your painkiller, Feb. 22

The dark side of your painkiller, Feb. 22

This article has helped to raise awareness of an important health safety issue: a simple mistake with acetaminophen can cause death. Taking too much of almost any medicine can cause harm or death. So why so much concern about a drug that most people agree is safe and effective when used correctly? The reasons relate not only to the properties of the drug and the frequency of its use, but also to the way it is marketed.

Raising awareness of 'umbrella names'

- “The use of ‘umbrella names’ for marketing purposes is confusing to consumers.”
- “This term refers to the use of the same brand name for products that contain different ingredients.”
- “Consumers must not assume that they know what a product contains just because it carries a familiar brand name.”

Available from https://www.thestar.com/opinion/letters_to_the_editors/2014/03/04/drug_umbrella_names_confuse_users.html



Risk-Minimization Strategies

Table 1. Selected risk-minimization strategies

| Risk-Minimization Strategy | Considered in the Acetaminophen Safety Review⁶ | Implemented in Other Jurisdictions |
|--|---|---|
| Add warnings to packages and inserts | Yes – to strengthen and improve product labelling | Yes (US, ⁶ UK ⁶) |
| Use blister packs | No | Yes (UK ⁹) |
| Limit package size | Yes | Yes (UK, ¹⁰ AU, ¹¹ NZ ⁶) |
| Limit the amount of acetaminophen contained in prescription products | Yes – limit amount of acetaminophen contained in opioid combination products | Yes (US ¹²) |
| Include an accurately calibrated dose-delivery device with all pediatric liquid acetaminophen-containing products | Yes – recommended in 2016 guidance ¹³ | Yes (US, ¹⁴ UK ⁶) |
| Reduce the maximum recommended daily dose | Yes – but not implemented as a result of stakeholder feedback | No – not implemented by the FDA, but voluntarily by Johnson & Johnson in the US ⁷ |
| Limit all products to maximum 325 mg acetaminophen per unit dose | Yes – already in place for prescription products, but lacked sufficient support to be implemented for nonprescription products | Yes (US for prescription products) ⁶ |
| Develop and implement an education strategy | Yes | Yes (US, ⁶ UK ⁶) |

ISMP Canada Safety Bulletin, 2017, Acetaminophen: Preventing Harm through Safe Use. Available from: <https://www.ismp-canada.org/download/safetyBulletins/2017/ISMPCSB2017-04-Acetaminophen.pdf>




2016 Health Canada Labelling Standard

- **Clearer instructions on packages emphasizing**
 - the lowest effective dose should be used
 - the maximum daily dose should not be exceeded
 - precautions with alcohol
- **Enhanced display of information: “Contains Acetaminophen”**
- **Drug Facts Table (mandatory 2021)**
- **Calibrated dosing device for liquid products provided in package**

Health Canada Revised Guidance cited in: SMP Canada Safety Bulletin, 2017, Acetaminophen: Preventing Harm through Safe Use. Available from: <https://www.ismp-canada.org/download/safetyBulletins/2017/ISMPCSB2017-04-Acetaminophen.pdf>



Health Canada Revised Guidance Document: Acetaminophen Labelling Standard

 Health Canada / Santé Canada

September 15, 2016

Notice

Our file number:

Revised Guidance Document: Acetaminophen Labelling Standard

The final version of the Health Canada Revised *Guidance Document - Acetaminophen Labelling Standard* is now available. Comments and suggestions received from the consultation between September to December 2015 on the draft version of the guidance were reviewed and considered in the finalization of this document. The labelling standard has been revised based on the outcome of the 2014 acetaminophen review which recommended that the label include stronger alcohol consumption-related warnings, the recommendation that a dosing device be included with children's liquid products and more safety information with regards to the product's content. A copy of the Summary Safety Review - Acetaminophen - Liver Injury can be obtained at the following link: <http://www.hc-sc.gc.ca/dhp-mps/medeff/reviews-examens/acetaminophen-eng.php>.

This labelling standard replaces the October 28, 2009 *Acetaminophen Labelling Standard Guidance Document*. The updated labelling standard includes a Drug Facts Table that will provide safety information in an easy-to-read format and uses plain language, so that consumers can more easily identify products that contain acetaminophen, understand the risks of liver injury and use the products as directed. The table also includes alcohol-related directions and clearer identification of products that contain acetaminophen.

This final labelling standard is effective immediately for all submissions seeking a new market authorization. Holders of market authorizations for existing products are strongly encouraged to effect any necessary labelling changes as soon as possible by submitting an updated label for review via a Post-authorization Division 1 Change. By March 2018, Health Canada expects all products to comply with the new labelling standard and will take appropriate regulatory measures, as circumstances warrant, to deal with any products that remain on the market without updated labelling.

This standard should also be used to inform the labelling of products that contain acetaminophen in addition to other ingredients (other than caffeine and codeine as specified in the standard), but which would not be submitted to Health Canada under the Labelling Standard stream.

As with any Guidance Document or Labelling Standard, alternate approaches may be acceptable provided they are supported by adequate justification and data. In these cases, an application outside of the Labelling Standard should be submitted.

Stronger, clearer labels for over-the-counter acetaminophen products to further address the risk of liver damage

Starting date: September 15, 2016
Posting date: September 15, 2016
Type of communication: Information Update
Subcategory: Drugs, Affects children, pregnant or breast feeding women
Source of recall: Health Canada
Issue: Labelling and Packaging
Audience: General Public
Identification number: RA-60198

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Issue

OTTAWA – Health Canada is releasing an updated [Labelling Standard](#) for over-the-counter acetaminophen products to help consumers use these products more safely. Product packages will include clearer instructions and stronger warnings to help reduce the potential for liver damage. This change is one of a number of steps Health Canada is taking in light of a [safety review](#) released in 2015.

Acetaminophen is a drug used in a wide range of non-prescription and prescription products, including headache and pain remedies, allergy medicines, cold remedies, and opioid pain relievers. With hundreds of different products available, it is one of the most commonly used pain and fever relievers in Canada.

Acetaminophen is used safely by the vast majority of Canadians. But like most health products, it can have risks, especially if too much is taken or if it is taken for longer than directed. These risks include liver damage, which in severe cases can lead to liver failure and even death.

Improvements to the Labelling Standard include:

- clearer instructions on packages that emphasize the importance of using the lowest effective dose; not exceeding the recommended daily maximum (which is 4,000 mg for adults) in a 24-hour period; using these products for no more than five days for pain or three days for fever; and not mixing them with alcohol if drinking three or more drinks in a day;
- displaying the words "contains acetaminophen" in bold, red text in the top right corner of the front of the package to make it easier for consumers to know if a product contains this drug;
- a new [Drug Facts](#) table for packages to provide product instructions, warnings and other safety information in a consistent, quick-reference format; and
- a recommendation that all children's liquid products include a calibrated dosing device, so parents and caregivers can be sure that they're giving their child the right amount.

The revised standard and the recommendation for children's dosing devices address recommendations coming out of the safety review. As an added safeguard, Health Canada is also issuing a [Notice to Industry](#) advising of a policy to limit the amount of acetaminophen in prescription combination

Available from: <https://www.canada.ca/en/health-canada/services/drugs-health-products/drug-products/applications-submissions/guidance-documents/revised-guidance-document-acetaminophen-labelling-standard.html> and <http://healthycanadians.gc.ca/recall-alert-rappel-avis/hc-sc/2016/60198a-eng.php>



Principal Display Panel requirements


Declaration of acetaminophen on the product label:

- **Principal display panel:**
 - For single ingredient products:
 - **“Contains Acetaminophen”** should appear in **bold** font type, font size 10 and in **red** text with a white background in the top right corner of the label.
 - For multi-ingredient products:
 - **“Contains Acetaminophen and other Ingredients”** should appear in **bold** font type and font size 10 in the top right corner of the label. In addition, the text for **“Contains Acetaminophen”** should appear in **red** with a white background.
 - For small package sized products:
 - Consideration will be given for products with small package size. However, the text for **“Contains Acetaminophen”** should appear prominently in **bold** font type in **red** with a white background in the top right corner of the label.

Health Canada will require drug makers to print 'Contains acetaminophen' in bold, red lettering on the product label. (Health Canada)



Drug Facts Table

| Drug Facts | |
|---|--|
| Active ingredient (in each dosage unit) acetaminophen 325 mg | Purpose (This relieves, does not relieve) |
| Uses: • Reduces fever • Temporarily relieves mild to moderate aches and pains (e.g., headache, rheumatoid arthritis, sore throat, neuralgia or flu) • Temporary relief of menstrual cramps • Relieves soreness and stiffness • Reduces hot flashes • Relieves cold and flu • Anesthetics | |
| Warnings: Liver warning: Acetaminophen may cause serious or possibly fatal liver damage if you take more than the recommended dose in 24 hours, with other drugs containing acetaminophen, or while drinking 3 or more alcoholic drinks every day (total alcohol only). Exceeding of liver damage may include: yellow skin, dark urine, dark stool, itching, nausea, vomiting, stomach pain, unusual bruising, loss of appetite. Allergy alert: Acetaminophen may cause serious skin reactions. Symptoms may include: hives, swelling, • Rash: If any of the above listed symptoms occur, stop use and seek medical help right away. | |
| Do not use: With any other drug containing acetaminophen. If you are already on acetaminophen or any other ingredient in this product, if you are not sure whether a drug contains acetaminophen, ask a doctor or pharmacist. | |
| Ask a doctor before use if you have liver or kidney disease. Ask a doctor or pharmacist before use if you take the blood thinning drug warfarin. | |
| Stop use and ask a doctor if: • you have for more than 7 days • fever has been less than 1 day. If pregnant or breastfeeding, ask a healthcare professional before use. | |
|  Keep out of reach of children. This package contains enough drug to seriously harm a child if given the | |





Drug Facts

Active ingredient (in each caplet) Purpose

Acetaminophen 325 mg Pain reliever/fever reducer

Uses

- temporarily relieves minor aches and pains due to
 - the common cold
 - headache
 - flu/fever
 - minor pain of arthritis
 - toothache
 - muscular aches
 - premenstrual and menstrual cramps
- temporarily reduces fever

Warnings

Liver warning: This product contains acetaminophen. Severe liver damage may occur if you take

- more than 4,000 mg of acetaminophen in 24 hours
- with other drugs containing acetaminophen
- 1 or more alcoholic drinks every day while using this product

Allergy alert: acetaminophen may cause severe skin reactions. Symptoms may include:

- skin redness
- blisters
- rash

If a skin reaction occurs, stop use and seek medical help right away.

Do not use

- with any other drug containing acetaminophen (prescription or nonprescription). If you are not sure whether a drug contains acetaminophen, ask a doctor or pharmacist.
- if you are allergic to acetaminophen or any of the inactive ingredients in this product.

Ask a doctor before use if you have liver disease

Ask a doctor or pharmacist before use if you are taking the blood thinning drug warfarin

Stop use and ask a doctor if

- pain gets worse or lasts more than 10 days
 - fever gets worse or lasts more than 3 days
 - new symptoms occur
 - redness or swelling is present
- These could be signs of a serious condition.

Drug Facts (continued)

If pregnant or breast-feeding, ask a health professional before use.

Keep out of reach of children.

Overdose warning: In case of overdose, get medical help or contact a Poison Control Center right away. (1-800-235-1333) Quick medical attention is critical for adults as well as for children, even if you do not notice any signs or symptoms.

Directions

■ do not take more than directed (see overdose warning)

| | |
|---------------------------------------|---|
| adults and children 12 years and over | <ul style="list-style-type: none"> ■ take 1 caplet every 4 hours while symptoms last ■ do not take more than 4 caplets in 24 hours, unless directed by a doctor ■ do not use for more than 10 days unless directed by a doctor |
| children under 12 years | ask a doctor |

Other information

- store between 20-25°C (68-77°F)
- do not use if caplet is opened or seal wrap or foil liner seal imprinted with "TYLENOL" is broken or missing

Inactive ingredients

croscellose gum, corn starch, FD&C red no. 40 aluminum lake, hypromellose, magnesium stearate, polyethylene glycol, powdered cellulose, pregelatinized starch, polyethylene glycol, stearic, sodium starch glycolate, titanium dioxide
*contains one or more of these ingredients

Questions or comments?

call 1-877-865-8445 (toll-free) or 215-275-8776 (collect)



Educate

facilitate and support learning and sharing to improve medication safety



Health Canada's Acetaminophen webpage



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Acetaminophen

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Safe use of medication for children

Ask your doctor about your child's medication

Automated external

Acetaminophen

Learn about acetaminophen, how to safely use it and its health risks, including potential overdose.

On this page

- [About acetaminophen](#)
- [Safe use](#)
- [Health risks](#)
- [Overdose](#)
- [For more information](#)

About acetaminophen

Acetaminophen is a drug ingredient found in over 600 different over-the-counter and prescription medicines. It's found in single or multiple ingredient products, under many different brand names, including:

- common pain relievers
- cold and flu medications

Available from: <https://www.canada.ca/en/health-canada/services/drugs-medical-devices/acetaminophen.html>



Let's talk about acetaminophen

Health Canada

Let's Talk About Acetaminophen

Acetaminophen is widely used in Canada to treat pain and fever. More than 700 over-the-counter and prescription medicines contain acetaminophen, including medications to treat muscle pain, allergies, cold and flu, and menstrual symptoms.

Acetaminophen is safe and effective when used as directed, but there is a limit to how much you can take in one day. Taking more than the recommended dose can cause severe or even fatal liver damage.

There are a number of steps you can follow to take acetaminophen safely:

Read the label

- Always read the product label carefully and follow the instructions.
- Know if the product contains acetaminophen.
- Talk to your doctor or pharmacist if you have questions.

Safe Use

- Take only one medication at a time that contains acetaminophen.
- Avoid taking the next dose too soon.
- Do not take more than the recommended amount at one time.

DYK

Acetaminophen is broken down by the liver? If you take too much—in one day or over several days—it can build up in your liver and become toxic.

Health Canada Santé Canada

Canada



DYK

Prolonged use, even at the recommended dose, also increases the risk of liver problems?

Know Your Dose

- Know the amount of acetaminophen you can take at one time.
- Know how often you can take the product and how many hours to wait before taking another dose.
- Always start with the lowest recommended dose.
- Keep track of how much you take daily.
- Taking more than the recommended dose will not provide more or faster relief.
- If you have liver disease or drink 3 or more alcoholic drinks every day, the maximum amount you can safely take may be less than what is listed on the product label.
- **Never take more than the maximum daily dose of 4,000 mg.**

8 extra strength tablets of 500 mg

or

12 regular strength tablets of 325 mg

If you take too much acetaminophen you could have liver damage and not be aware of it. Symptoms may not appear for many hours following an overdose. Call your local poison control centre immediately if you have taken more than the maximum daily dose.

DYK

In Canada there are approximately 700 hospitalizations each year for accidental overdoses involving acetaminophen?

DYK

Acetaminophen overdose is a leading cause of acute liver failure in Canada?

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Cat. 1413-9-02/2014-PDF (1) ISBN 978-0-606-06236-5 / Pub. 140714

Available from <https://www.canada.ca/en/health-canada/services/publications/drugs-health-products/let-s-talk-about-acetaminophen.html>



Let's talk about acetaminophen

Health Canada

Acetaminophen



Know your dose

The **maximum** recommended dose of acetaminophen for adults is **4,000 mg daily**

the same as...

 **8** extra strength tablets of 500 mg

or

 **12** regular strength tablets of 325 mg

Taking more than the recommended dose can lead to **severe or even fatal liver damage.**

To take acetaminophen safely, make sure you:

-  **ALWAYS READ** product labels carefully and follow the instructions.
-  **ASK** your doctor or pharmacist if you are unsure about your dose or have questions.
-  **KNOW** if your medications contain acetaminophen.
-  **NEVER TAKE** more than the maximum daily dose.
-  **AVOID TAKING** more than one product containing acetaminophen at the same time.
-  **IF YOU HAVE** liver disease or drink 3 or more alcoholic drinks every day, the maximum amount you can safely take may be less than what is listed on the product label.

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Available from: <https://www.canada.ca/content/dam/canada/health-canada/migration/healthy-canadians/publications/drugs-products-medicaments-produits/poster-acetaminophen-acetaminophene-affiche/alt/pub-eng.pdf>



Spotlight on Acetaminophen

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Help Prevent Harmful Medication Incidents
A component of the Canadian Medication Incident Reporting and Prevention System (CMIRPS).

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Get Medication Safety Tips

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- Keep a Medication List
- Brochures
- Frequently Asked Questions (FAQs)
- Go to Health Canada Advisories
- Poison Centres in Canada
- Helpful Links
- Newsletter

Medication Safety Tips

- View all Tips

Spotlight on Acetaminophen

SHARE

Acetaminophen is most commonly known by the brand name Tylenol, but it is also found in many over-the-counter drugs (for example including Excedrin, Atasol, Midol, NeoCitran, and NyQuil) and prescription drugs (for example, Percocet and Tylenol #3). In fact, according to Health's Canada's online Drug Product Database, there are more than 400 products containing acetaminophen on the Canadian market!

In proper doses, acetaminophen is a safe drug, but acetaminophen overdose is a common cause of acute liver failure. The recommended maximum daily dose of acetaminophen for healthy adults is 4 grams or 4,000 milligrams—the amount found in eight Tylenol Extra Strength tablets. For children, elderly patients and alcohol users, the maximum dose is much lower. Since many cough, cold and "flu" preparations contain acetaminophen to control fever and aches, it would be easy to take too much acetaminophen if you didn't check the ingredients carefully. The safe dose is easily exceeded when consumers take a little extra of one product or take a number of remedies that contain acetaminophen.

So before you reach for that packet of "hot lemon" or other non-prescription remedy, be sure to check the ingredients. The best advice is to read every label carefully to be sure you know the contents of any product you use. Know the maximum daily dose of acetaminophen for you and your family members and carefully monitor the amount taken. When taking any medication, remember that anything more than the recommended dose is an overdose. If in doubt, ask your pharmacist!

- SafeMedicationUse.ca Newsletter:
[Acetaminophen - Harm from Overdose Can Be Prevented](#)

Health Canada Resources:

- [Using acetaminophen safely](#)

SafeMedicationUse.ca webpage – Spotlight on Acetaminophen, Available from: https://safemedicationuse.ca/tools_resources/tips_acetaminophen.html



Newsletter for Consumers

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Consumers Can Help Prevent Harmful Medication Incidents

SafeMedicationUse.ca Newsletter

Volume 5 • Issue 1 • February 6, 2014

Acetaminophen – Harm from Overdose Can Be Prevented

Acetaminophen is a medicine used to treat pain and reduce fever. It is most commonly known by the brand name Tylenol, but it is also found in many nonprescription and prescription products with other names. Acetaminophen is safe and effective when it is used correctly. However, taking too much acetaminophen can harm your liver, possibly leading to liver failure or even death.

Through ISMP Canada's work with provincial coroners and chief medical examiners, SafeMedicationUse.ca has become aware of 2 fatal incidents involving acetaminophen. In each case, an adult died after taking too much acetaminophen. In one case, the consumer had been taking about 10 extra-strength acetaminophen tablets most days of the week. Each extra-strength tablet contained 500 mg of acetaminophen. This meant the consumer was taking 5000 mg (5 g) of acetaminophen per day. This is above the current maximum daily dose recommended for healthy adults in Canada. The consumer also drank alcohol, which increases the chances of harm to the liver.

Here are tips for consumers to help prevent harm when using medicines that contain acetaminophen:

- **Do not exceed the recommended maximum daily dose of acetaminophen.** The maximum daily dose is the total amount of a medicine that a person can safely take in one day. Information about the maximum daily dose of nonprescription products may be indicated on the label by wording such as "Do not take more than..." (see the example label in Figure 1). In Canada, the maximum daily dose of acetaminophen currently recommended for healthy adults is 4000 mg (4 g) per day.* However, the amount of acetaminophen that you can safely take each day may be lower, depending on your age, medical conditions, and the amount of alcohol you consume.




Figure 1 - Example of Extra Strength Tylenol medicine label (Image courtesy of Johnson & Johnson Inc.)

*Labelled recommendations for the maximum daily dose of acetaminophen may differ outside Canada.


SafeMedicationUse.ca Newsletter – www.safemedicationuse.ca Page 1 of 2

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SafemedicationUse.ca Newsletter, 2014, Acetaminophen – Harm from Overdose Can Be prevented, Available form: <https://safemedicationuse.ca/newsletter/downloads/201402NewsletterV5N1Acetaminophen.pdf>



Safety Bulletin for Health Care Providers



Institute for Safe Medication Practices Canada
REPORT MEDICATION INCIDENTS
Online: www.ismp-canada.org/err_index.htm
Phone: 1-866-544-7672

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Canadian Medication Incident Reporting System
Supports the safe use of medication in Canada

ISMP Canada Safety Bulletin

Volume 17 - Issue 4 - April 27, 2017

Acetaminophen: Preventing Harm through Safe Use

- Review the patient's medical and medication-use history to assess whether the patient has risk factors warranting a reduction in the acetaminophen dosage.
- Use the Health Canada guide "Let's Talk About Acetaminophen" to educate patients on how to use acetaminophen safely.
- Ensure that doses for pediatric patients are calculated using an accurate weight and that an appropriate measuring device is used to administer all liquid doses.

Despite its reputation for safety, acetaminophen has been identified as the leading cause of liver failure in Canada; approximately 4500 Canadians are hospitalized for acetaminophen overdose annually, and about 6% of these patients experience liver injury.¹ Injury to the liver, which has occurred with both intentional and unintentional acetaminophen overdoses, may be irreversible.

Acetaminophen is a commonly used analgesic that is widely available in either single- or multiple-ingredient products. As of early 2017, almost 500 acetaminophen-containing products were marketed in Canada, with over 350 of them available as nonprescription, over-the-counter (OTC) products.² Health Canada recently estimated that 4 billion dosage units of acetaminophen are sold in the country annually.¹

This bulletin highlights, for both healthcare professionals and manufacturers, key safety efforts, important resources, and strategic recommendations based on recent Health Canada initiatives supporting the safe use of acetaminophen in Canada.

Canadian Initiatives to Support Safe Use of Acetaminophen

Health Canada has conducted safety reviews (described in more detail below), issued public advisories, and instituted changes to the labelling requirements for OTC products containing acetaminophen. Practitioners and the public can find links to these and other related resources on a Government of Canada webpage dedicated to acetaminophen safety.³

ISMP Canada's efforts to support the safe use of acetaminophen have included publishing an acetaminophen newsletter as part of its consumer medication safety program at SafeMedicationUse.ca,⁴ launching [Spotlight on Acetaminophen](#),⁵ a webpage dedicated to acetaminophen safety, and publicizing acetaminophen safety strategies on social media.

Health Canada's Acetaminophen Safety Review and Recent Regulatory Changes

In 2009, there was an initial safety review of non-prescription acetaminophen products which led to updated labelling standards that included increased warnings about the potentially serious and possibly fatal risk of liver injury in the event of

ISMP Canada Safety Bulletin – www.ismp-canada.org/ISMPSafetyBulletins.htm 1 of 7

ISMP Canada Safety Bulletin, 2017, Acetaminophen: Preventing Harm through Safe Use. Available from: <https://www.ismp-canada.org/download/safetyBulletins/2017/ISMPCSB2017-04-Acetaminophen.pdf>



Media Key Messages



THE
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CANADA

Health Canada issues new labelling rules for acetaminophen



KELLY GRANT > HEALTH REPORTER
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Health Canada is imposing new labelling rules aimed at reducing the risk of liver damage caused by taking too much acetaminophen, best known as the drug in Tylenol.

Health Canada began considering the changes two years ago after a safety review found acetaminophen, considered one of the safest pain relievers available if taken properly, leads to more than 250 serious liver injuries and 4,000 hospitalizations for overdoses in Canada every year.

The new labelling standard that Health Canada announced Thursday will require drug companies to:

- Print clearer warnings about safe doses, including a warning not to mix the drug with more than three alcoholic drinks a day;
- Mark packages with the words “contains acetaminophen” in bold red text;
- Include a calibrated dosing device in products for children so parents can be sure they are not accidentally exceeding the recommended limits.

Available from: <https://www.theglobeandmail.com/news/national/health-canada-puts-new-labelling-rules-on-acetaminophen/article31894465/>



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You may not know that acetaminophen is in a product unless you look at the ingredients. (Institute for Safe Medication Practices Canada)

Available from: <https://www.cbc.ca/news/health/acetaminophen-toxicity-health-canada-1.3764672>

Image provided by ISMP Canada to help demonstrate why we needed the new label standard

- Multiple products containing acetaminophen
- Difficult to identify acetaminophen



Social Media Campaign - twitter



GovCanHealth 
@GovCanHealth

Drinking [#alcohol](#) while taking [#acetaminophen](#) can cause liver damage. Learn more: ow.ly/vDRK30h4PQb



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5 Questions to Ask, and Acetaminophen

5 QUESTIONS TO ASK ABOUT YOUR MEDICATIONS when you see your doctor, nurse, or pharmacist.

1. CHANGES?

Have any medications been added, stopped or changed, and why?

2. CONTINUE?

What medications do I need to keep taking, and why?

3. PROPER USE?

How do I take my medications, and for how long?

4. MONITOR?

How will I know if my medication is working, and what side effects do I watch for?

5. FOLLOW-UP?

Do I need any tests and when do I book my next visit?



Keep your medication record up to date.

Remember to include:

- ✓ drug allergies
- ✓ vitamins and minerals
- ✓ herbal/natural products
- ✓ all medications including non-prescription products

Ask your doctor, nurse or pharmacist to review all your medications to see if any can be stopped or reduced.



Visit safemedicationuse.ca for more information.

Canadian Society of Hospital Pharmacists

Société canadienne des pharmaciens d'hôpital

CANADIAN PHARMACEUTICAL ASSOCIATION / ASSOCIATION DES PHARMACIENS DU CANADA

SafeMedicationUse.ca



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TECH REFRESHER

Raising awareness of acetaminophen

ACETAMINOPHEN IS WIDELY USED IN Canada to treat pain and fever. While it is most commonly known by the brand name Tylenol, more than 700 over-the-counter (OTC) and prescription medicines contain acetaminophen, says Health Canada. These include medications to treat muscle pain, allergies, cold and flu, and menstrual symptoms.

The drug is safe and effective when used as directed, but there is a limit to how much should be taken in one day. According to the Institute for Safe Medication Practices Canada (ISMP Canada), acetaminophen has been identified as the leading cause of liver failure in Canada; approximately 4,500 Canadians are hospitalized for acetaminophen overdose annually, and about six per cent of these patients experience liver injury that may be irreversible.

Alice Watt, a pharmacist as well as medication safety specialist at ISMP Canada, says community pharmacy technicians and assistants can help prevent overdoses by drawing patients' attention to medications that contain acetaminophen, whether in a

prescription drug or OTC medication. "If the pharmacy technician or assistant notices that a patient has a product that contains acetaminophen, they could flag it to the pharmacist for counsel, or offer the patient the brochure 'Let's talk about acetaminophen,'" available on Health Canada's acetaminophen information webpage at <https://www.canada.ca/en/health-canada/services/publications/drugs-health-products/let-s-talk-about-acetaminophen.html>.

"For example, every time you give out a Tylenol 1 bottle, you can provide that pamphlet with it," Watt suggests.

Hospital pharmacy technicians can also play an important safety role when performing a Best Possible Medication History (BPMH).

by asking patients about any OTC drugs they are taking regularly. "BPMH is something that med rec technicians do," says Watt. "If the patient is taking an OTC drug that contains acetaminophen, ask how many they would take on average per day," Watt suggests. "That's an important piece of information. I usually ask: 'On a really bad day, how many would you take?' How many have you taken recently?" Because that might be a factor as to why they're in the hospital.

While it's not always possible in a community pharmacy setting to flag patients purchasing OTC products that contain acetaminophen, technicians and assistants who seize any opportunity to do so will be making a significant contribution to safer use of these medications.

RESOURCES

- Health Canada webpage on acetaminophen: <https://www.canada.ca/en/health-canada/services/drugs-medical-devices/acetaminophen.html>
- Spotlight on acetaminophen, ISMP Canada: https://safemedicationuse.ca/tools_resources/tips_acetaminophen.html

FIVE QUESTIONS FOR PATIENTS TO ASK

ISMP Canada has collaborated with the Canadian Pharmacists Association, the Canadian Society for Hospital Pharmacists, Canadian Patient Safety Institute, and Patients for Patient Safety Canada to develop a set of five questions to help patients and caregivers start a conversation about medications with their healthcare provider, as follows:

1. **Changes?** Have any medications been added, stopped or changed, and why?
2. **Continue?** What medications do I need to keep taking, and why?
3. **Proper use?** How do I take my medications, and for how long?
4. **Monitor?** How will I know if my medication is working, and what side effects do I watch for?
5. **Follow-up?** Do I need any tests, and when do I book my next visit?

Watt says pharmacy technicians and assistants can promote safe medication use by introducing this tool to patients. "That should prompt patients to ask these questions of their pharmacist," she says.

"Acetaminophen falls into the proper use question," adds Watt. "How do I properly use this medicine that has acetaminophen in it? And what to monitor."

Pharmacists can download a printable form of "The Five Questions" for distribution, and include their logo upon request, at <https://www.ismp-canada.org/medrec/5questions.html>.



Generic Medications: Addressing Common Patient Concerns with Confidence.

Includes three video vignettes, demonstrating how a Pharmacy Technician and Pharmacist can effectively respond to common patient questions about generic drugs.

TevaPharmacySolutions.com

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Available from: <https://www.ismp-canada.org/medrec/5questions.htm> and https://www.ismp-canada.org/download/MedRec/5questions/TT-NEWS-2017-Sept_FINAL.pdf, page 4



Opioid Crisis and Pain Management



Managing pain after wisdom teeth removal: Your questions answered

1. Changes?

Pain after wisdom teeth removal is common. Non-opioid and opioid medications have been prescribed to treat your pain.



FIRST TRY acetaminophen (Tylenol®) and/or ibuprofen (Motrin®, Advil®) or naproxen (Aleve®, Naprosyn®) taken at regular intervals to manage your pain. Talk to your dentist, surgeon or pharmacist to find the right medications for you and to help you with the pain control plan. If you are still in lot of pain, then use the opioid that has been prescribed for you. Opioids reduce pain but will not take away all your pain. Ask about other ways to deal with pain including using ice.

You have been prescribed an opioid (narcotic): _____

2. Continue?

Opioids are usually required for less than 3 days.

As you continue to recover, your pain should be less day by day and you will need less opioids. Get in touch with your dentist, surgeon or pharmacist if your pain does not improve.

3. Proper Use?

Overdose and addiction can occur with opioids.

Use the lowest possible dose for the shortest possible time for all pain medications. Discuss the need to avoid driving and using heavy machinery while taking opioids with your dentist/surgeon. It can be dangerous to combine opioids with alcohol or sleeping/anti-anxiety pills (e.g. lorazepam [Ativan®], clonazepam [Rivotril®]).

4. Monitor?

Side effects from opioids include: constipation, drowsiness, nausea and dizziness.

Contact your healthcare provider if you have severe dizziness or trouble staying awake. Taking opioids with alcohol, sleeping/anti-anxiety pills or cannabis (marijuana) can increase your risk of side effects. Let your dentist, surgeon or pharmacist know if you are taking any of these substances.

5. Follow-Up?

Ask your prescriber when your pain should get better.

If your pain is not improving as expected, or if your pain is not well controlled, talk to your dentist/surgeon or pharmacist.

To find out more, visit: OpioidStewardship.ca

It is important to:



Never share your opioid medication with anyone else.



Store your opioid medication in a secure place; out of reach and out of sight of children, teens and pets.



Ask about other options available to treat pain.



Take all unused opioids back to a pharmacy for safe disposal. Talk with your pharmacist if you have questions. For locations that accept returns: ☎ 1-844-535-8889 🌐 healthsteward.ca

Did you know?



Younger students, particularly those in grade 7 and 8, are using opioids non-medically in far greater numbers than cannabis.

More than 2/3 students (67%) using opioid painkillers non-medically, reported getting the medication from home.
— The Centre for Addiction and Mental Health (CAMH), 2018

About 17 Canadians are hospitalized each day with opioid poisoning.
— Canadian Institute for Health Information (CIHI), 2018

Notes:

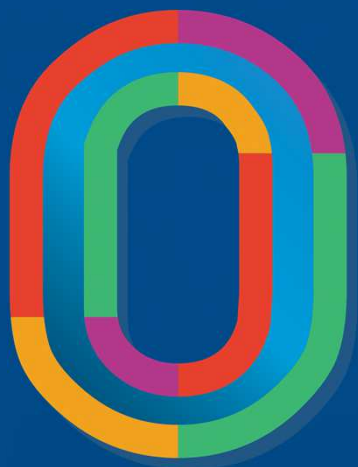
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Balancing harms / risks of available therapies:

- Acetaminophen
- NSAIDS
- Opioids

Available from: <https://www.ismp-canada.org/download/OpioidStewardship/WisdomTeethRemoval-EN.pdf>



ZERO
PREVENTABLE HARM
FROM MEDICATIONS

Thank you
Any Questions?

A Key Partner in the Canadian Medication Incident Reporting and Prevention System

