

## Summary of Labelling Standards

### October 2019 labelling standard

#### For outer and inner labels of all acetaminophen products

**KEEP OUT OF THE REACH OF CHILDREN.** (Must be preceded by a prominently displayed symbol that is octagonal in shape, conspicuous in colour and on a background of a contrasting colour.)

- This package contains enough drug to seriously harm a child (if greater than 3.2 grams of acetaminophen in the package). (Must be preceded by a prominently displayed symbol that is octagonal in shape, conspicuous in colour and on a background of a contrasting colour.)
- **DO NOT USE** with other drugs containing **acetaminophen**.

#### [For adult use products only]:

- **ADULT USE ONLY. DO NOT** take more than the recommended dose unless advised by your doctor. Use the smallest effective dose. Taking more than the maximum daily dose may cause **severe or possibly fatal liver damage**.

#### [For children and infants' (<12 years) products only]:

- **DO NOT** take more than the recommended dose unless advised by your doctor. Taking more than the maximum daily dose may cause **severe or possibly fatal liver damage**.

**All of the following warnings may appear on an insert or inner panels if it can be demonstrated that space is limited on the packaging. Note that the packaging must carry clear instructions to access the insert or inner panels:**

- Do not take if allergic to acetaminophen.
- **Consult a doctor if:**
  - you develop allergic reactions such as wheezing, rash or itching;
  - your symptoms last for more than five days, or fever lasts more than 3 days.
- **In Case of Overdose:** call a Poison Control Centre or doctor immediately, even if you do not notice any signs or symptoms. Within the first 24 hours you may experience increased sweating, nausea, vomiting, stomach pain, and loss of appetite.

Ask a doctor or a pharmacist before use if you:

- **[For adult use products only]:**
  - are pregnant or breastfeeding
  - have chronic alcoholism
- have a serious liver or kidney disease
- use any other medications including natural health products, prescription drugs, salicylates or other pain and fever relief medications (nonsteroidal anti-inflammatory drugs (NSAIDs))

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### OTHER REQUIREMENTS

#### For all products

- Declaration of ingredients:
  - Single ingredient products and/or ones for which a compendial standard exists must declare the proper name of the finished product on the front panel of all labels, immediately preceding or following the brand name in a font size not less than ½ the size of the brand name.
  - Multiple ingredient products for which there is no compendial standard must state the following on the front panels of all labels:
    - Contains acetaminophen and other ingredients
  - All products must declare the active ingredients on the inner and outer labels, and clearly label these as “active” or “medicinal” ingredients.

#### Legibility of labels:

Although no specific type size is mentioned in the *Regulations*, Section A.01.016 specifies that all information required to appear on a label must be:

- Clearly and prominently displayed; and
- Readily discernible to the purchaser or consumer under the customary conditions of purchase and use

A person with normal vision, or those with corrective glasses that restore normal vision, should be able to read the information without straining. The colour, contrast, the position, and the spacing of the information are all to be taken into consideration in complying with these requirements. A type size of 10 point for text and 9 point minimum for tables are recommended for any analgesic product package inserts, in keeping with section 2.2 of Health Canada’s *Guidance to Industry: Product Monograph*. It is recommended that analgesic product labels have a minimum of font size 9.

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### September 2016/March 2018 Labelling Standard

#### For outer and inner labels of all acetaminophen products

- **KEEP OUT OF THE REACH OF CHILDREN.** (Must be preceded by a prominently displayed symbol that is octagonal in shape, conspicuous in colour and on a background of a contrasting colour.)
- This package contains enough drug to seriously harm a child (if greater than 3.2 grams of acetaminophen in the package). (Must be preceded by a prominently displayed symbol that is octagonal in shape, conspicuous in colour and on a background of a contrasting colour.)
- **DO NOT USE** with other drugs containing **acetaminophen**. If you are not sure whether a drug contains acetaminophen, ask a doctor or pharmacist.
- **DO NOT USE** if you are allergic to acetaminophen or any other ingredient in this Product

**Liver warning** (should be **bold** font type and in **red** text): This product contains acetaminophen. Maximum daily dose is X <tablets/caplets> (XX mg) in 24 hours.

**Severe or possibly fatal liver damage** may occur if you take:

- more than the recommended dose in 24 hours;
- with other drugs containing acetaminophen;
- while drinking three (3) or more alcoholic drinks every day (*for adult use products only*).

Symptoms of liver damage may include:

- yellowing of the skin/eyes, dark urine;
- sweating, nausea, vomiting, stomach pain;
- unusual tiredness, and/or loss of appetite.

**Allergy alert:** acetaminophen may cause serious skin reactions. Symptoms may include:

- skin reddening, blisters, rash.

**If any of the above noted symptoms occur, stop use and seek medical help right away.**

**Ask a doctor before use if you:**

- have a liver or kidney disease.

**Ask a doctor or pharmacist before use if you:**

- are taking Warfarin-containing blood thinning drugs;
- are pregnant or breast feeding.

**Stop use and ask a doctor if:**

- pain lasts for more than five (5) days
- fever lasts for more than three (3) days

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**In Case of Overdose:** Call a Poison Control Centre or get medical help right away. Quick medical attention is critical even if you do not notice any signs or symptoms.

### OTHER REQUIREMENTS

#### For all products

#### 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.

##### Legibility:

Although no specific type size is mentioned in the *Food and Drug Regulations*, Section A.01.016 specifies that all information required to appear on a label must be:

- Clearly and prominently displayed, and
- Readily discernible to the purchaser or consumer under the customary conditions of purchase and use.

A person with normal vision, or those with corrective glasses that restore normal vision, should be able to read the information without straining. The colour, contrast, the position, and the spacing of the information are all to be taken into consideration in complying with these requirements.