# Injectable Compounded Product Label Design for Safety

## INTRODUCTION

**The Injectable Compounded Product Label Design for Safety is intended to:**

- Heighten awareness of the characteristics of a safe label for injectable compounded[i] products;
- Assist compounded product providers (e.g., commercial compounders, hospitals) to evaluate label content and design for injectable compounded products;
- Provide a **general checklist** for injectable compounded product label design; and
- Provide **specific checklists** for select high alert products
  - epidural medications (label examples are provided)
  - intravenous opioids (label examples are provided)

The checklists should be considered within the context of how the medications will be used. It is anticipated that new research on various characteristics presented in the checklists will become available in the future, and revisions may be warranted to integrate such new information.

**Why are checklists for injectable compounded product labels needed?**

Label content and design have been identified as contributing factors to numerous medication incidents.[1] It is crucial to consider the intended use of the product and the needs of the end user when designing product labels.[2] Labels should include critical information that will guide the process for administration, including the use of infusion pumps.

There has been increased attention to compounded medication labelling in the oncology setting and beyond.[3] Additionally, hospitals are increasingly turning to external compounders (e.g., specialty pharmacies, compounding facilities, and manufacturers) to support availability and integrity of products in order to ensure compliance with published guidance and requirements for sterile products.[4,5,6,7] Use of external vendors may increase variability in label information content and design when compared to in-house preparations in hospitals, therefore this document has been developed to help standardize safe label design for all compounded product providers.

**About ISMP Canada's safety checklists**

This document has been informed by a prospective risk assessment project undertaken by an Ontario hospital. The checklists were developed with stakeholder input and tested in February 2017.

The general checklist and the specific checklists include assessment items divided into 4 sections: label content; label design; label position; and other considerations for injectable compounded products.

The checklist items are not intended to represent a regulated standard of practice. Some of the items represent innovative practices and system enhancements that are not yet widely implemented. However, their value in reducing errors is grounded in scientific research and expert analysis of medication errors and their causes. Medication safety checklists are intended for internal use and can inform regulatory standards.



[i] Health Canada considers compounding to be the following: The combining or mixing together of two or more ingredients (of which at least one is a drug or pharmacologically active component) to create a final product in an appropriate form for dosing. It can involve raw materials or the alteration of the form and strength of commercially available products. It can include reformulation to allow for a novel drug delivery. Compounding does not include mixing, reconstituting, or any other manipulation that is performed in accordance with the directions for use on an approved drug's labelling material (Aside added: "within the normal practice of pharmacy").

Health Canada. Health Products and Food Branch Directorate. Policy on Manufacturing and Compounding Drug Products in Canada. POL-0051 [Internet]. Ottawa (ON): 2009 Jul 26 [cited 2016 May]. Available from: http://www.hc-sc.gc.ca/dhp-mps/alt_formats/hpfb-dgpsa/pdf/compli-conform/pol_0051-eng.pdf

# Injectable Compounded Product Label Checklist (General Checklist)

| | |
|---|---|
| YES | This item is **fully implemented** for injectable compounded product labels |
| PARTIAL | This item has been **partially implemented** for injectable compounded product labels |
| NO | There has been **no activity** to implement this item for injectable compounded product labels |
| N/A | Not applicable; selected items only |

## 1. LABEL CONTENT

| | | YES | PARTIAL | NO | N/A |
|---|---|---|---|---|---|
| 1.1 | The label does not contain error-prone abbreviations, symbols, or dose designations.[2,8]<br>**See FAQ 1.1** | | | | |
| 1.2 | The label prominently identifies the route of administration using only affirmative statements (e.g., For Intravenous Use Only).[2,9]<br>**See FAQ 1.2** | | | | |
| 1.3 | The label includes the total volume in the container (including overfill and additive volume *when required* for exact volume doses). | | | | |
| 1.4 | The strength is expressed in both total dose per total volume and dose per mL. The total dose per total volume is more prominent than, and in close proximity to, the dose per mL.[2]<br>**Exception:** See the *Compounded Epidural Medication Label Checklist* | | | | |
| 1.5 | The base solution used to prepare the compounded product is noted on the label (e.g., "… in 50 mL sodium chloride 0.9%"). | | | | |
| 1.6 | The label includes the date beyond which the preparation cannot be used and must be discarded.[5,6] | | | | |
| 1.7 | The label includes storage requirements (e.g., Protect from light).[5,6] | | | | |
| 1.8 | An automated identifier (e.g., bar code) is provided in addition to the human-readable text.[2,10] | | | | |
| 1.9 | The label contains only the information needed to ensure safe use[5,11,12] and meet regulatory requirements. Non-essential information is minimized.[6,12] | | | | |
| 1.10 | The label includes appropriate warning statements.<br>**See FAQ 1.10 for select examples**<br>*Choose N/A if the compounded product does not require a warning.* | | | | |

## 2. LABEL DESIGN

| | | YES | PARTIAL | NO | N/A |
|---|---|---|---|---|---|
| 2.1 | Critical information (e.g., drug name, dose) appears first on the label and is positioned to distinguish it from non-critical information (e.g., vendor name). | | | | |
| 2.2 | A non-condensed, sans serif type style in the largest point size possible is used.[2] A minimum of 12 point is recommended for critical information. | | | | |
| 2.3 | Mixed case lettering is used to enhance readability. As an exception, full capitalization may be used for trade names (e.g., DILAUDID).[2] | | | | |
| 2.4 | TALLman lettering is used to differentiate look-alike, sound-alike drug names, where recommended.[2]<br>**See FAQ 2.4** | | | | |
| 2.5 | Critical information (e.g., drug name, dose) is given prominence using contrasting type characteristics (e.g., bolding, colour).[2] | | | | |
| 2.6 | There is adequate white space between text characters and lines of text to enhance readability.[2,13]<br>**See FAQ 2.6** | | | | |

| | | | | | |
|---|---|---|---|---|---|
| **2.7** | There is adequate contrast between type colour and label background to enhance readability.[2,14] **See FAQ 2.7** | | | | |
| **2.8** | There is adequate space for all data fields (including a bar code). This may require a text wrap option or continuation of text on an additional label.[2] | | | | |
| **2.9** | Logos and trade dress on product labels do not distract the user or impede the effective communication of key information to the user.[2] | | | | |
| **2.10** | Labels and inks used are durable enough to withstand normal handling (e.g., resistant to isopropyl or ethyl alcohol).[2] | | | | |

## 3. LABEL POSITION

| | | YES | PARTIAL | NO | N/A |
|---|---|---|---|---|---|
| **3.1** | The label position is standardized on the solution container to optimize text and bar code readability when the container is connected to the pump.[2,6] | | | | |
| **3.2** | Syringe labels are positioned so that they can be read from left to right when the syringe plunger is on the right side (i.e., labels are positioned so that the left edge of the label is proximal to the tip of the syringe). This allows users to "read up" when the syringe is inserted into the pump. **See FAQ 3.2** | | | | |
| **3.3** | Syringe labels are positioned to ensure readability of syringe volume graduations.[15,16] **See FAQ 3.3** | | | | |
| **3.4** | Bag labels are placed on the same side with the name of the bag and/or base solution. The lot number and expiry date of the base solution are still visible, where possible.[15] **See FAQ 3.4** | | | | |
| **3.5** | Bag labels are oriented to ensure readability when the bag is hung for administration.[2] | | | | |
| **3.6** | Label placement on syringe or bag does not obscure visibility of contents (e.g., to check for precipitate).[6,16] | | | | |
| **3.7** | A duplicate label is applied to any outer packaging or over wrap that impairs visibility of the product container and label.[15] | | | | |

## 4. OTHER CONSIDERATIONS

| | | YES | PARTIAL | NO | N/A |
|---|---|---|---|---|---|
| **4.1** | Compounded products are ordered using predefined order sets approved by an interdisciplinary committee, where appropriate. *Choose N/A if your organization is a commercial compounder.* | | | | |
| **4.2** | Master formulas for compounded products include a sample label and auxiliary labels to be applied to the medication container. *Choose N/A if your organization is a commercial compounder.* | | | | |
| **4.3** | Information required by end users is provided in a consistent sequence and format to support "mapping" between order sets, automated dispensing cabinet display screens, medication administration records, infusion pump programming screens and libraries, and the medication label. *Choose N/A if your organization is a commercial compounder.* | | | | |
| **4.4** | User (e.g., nurse, physician) testing of the legibility and readability of injectable compounded product labels is conducted, ideally using a simulation process that replicates actual practice.[2] | | | | |

| | | | | | |
|---|---|---|---|---|---|
| **4.5** | Changes to pumps, pump libraries and labels are managed in a systematic manner using quality improvement principles, and only done by designated staff following institution policy or standards of practice. *Choose N/A if your organization is a commercial compounder.* | | | | |
| **4.6** | Label content and design is re-evaluated as needed (e.g., identified safety risk or whenever there is a change in infusion equipment). | | | | |

# Epidural Medications

**Why is a checklist for compounded epidural medication product labels needed?**

Medications commonly administered by the epidural route include local anaesthetics and opioids. A key risk with these products is that they physically resemble products for intravenous administration (i.e., they are provided in bags or parenteral syringes).[17]

Local anaesthetics can be cardiotoxic if administered intravenously and fatalities have resulted when these mix-ups have occurred.[18]

Safe label content and design for compounded epidural products can help mitigate risk of errors and harm.

# Compounded Epidural Medication Label Checklist

| | |
|---|---|
| YES | This item is **fully implemented** for compounded epidural medication labels |
| PARTIAL | This item has been **partially implemented** for compounded epidural medication labels |
| NO | There has been **no activity** to implement this item for compounded epidural medication labels |
| N/A | Not applicable; selected items only |

## 1. LABEL CONTENT

| | | YES | PARTIAL | NO | N/A |
|---|---|---|---|---|---|
| 1.1 | The label does not contain error-prone abbreviations, symbols, or dose designations.[2,8] **See FAQ 1.1** | | | | |
| 1.2 | The label prominently identifies the route of administration using only affirmative statements (e.g., For Epidural Use Only).[2,9] **See FAQ 1.2** | | | | |
| 1.3 | The anaesthetic strength is expressed in percentage (e.g., bupivacaine 0.1%), rather than in dose per mL or dose per total volume.[17] **See FAQ 1.3** | | | | |
| 1.4 | The opioid strength is expressed in dose per mL rather than total dose per total volume (e.g., fentanyl 2 mcg/mL), unless the total dose per total volume is needed for pump programming.[17] | | | | |
| 1.5 | The label includes the total volume in the container (including overfill and additive volume *when required* for exact volume doses). | | | | |
| 1.7 | The base solution used to prepare the compounded product is noted on the label (e.g., "… in 50 mL sodium chloride 0.9%"). | | | | |
| 1.8 | The label includes the date beyond which the preparation cannot be used and must be discarded.[5,6] | | | | |
| 1.9 | The label includes storage requirements (e.g., Protect from light).[5,6] | | | | |
| 1.10 | An automated identifier (e.g., bar code) is provided in addition to the human-readable text.[2,10] | | | | |
| 1.11 | The label contains only the information needed to ensure safe use[5,11,12] and meet regulatory requirements. Non-essential information is minimized.[6,12] | | | | |
| 1.12 | The label includes appropriate warning statements. *Choose N/A if the compounded product does not require a warning.* | | | | |

## 2. LABEL DESIGN

| | | YES | PARTIAL | NO | N/A |
|---|---|---|---|---|---|
| **2.1** | Labels for epidural products are distinctly different from labels used on products to be administered intravenously (e.g., yellow-coloured labels, use of auxiliary labels).[17] | | | | |
| **2.2** | Critical information (e.g., drug name, dose) appears first on the label and is positioned to distinguish it from non-critical information (e.g., vendor name). | | | | |
| **2.3** | The anaesthetic agent is listed first on the label followed by the opioid (e.g., bupivacaine 0.1% and fentanyl 2 mcg/mL).[17] *Choose N/A if your organization does not compound epidural products with more than one medication.* | | | | |
| **2.4** | The name of the anaesthetic agent is listed before the strength (e.g., bupivacaine 0.1% *not* 0.1% bupivacaine).[17] | | | | |
| **2.5** | A non-condensed, sans serif type style in the largest point size possible is used.[2] A minimum of 12 point is recommended for critical information. | | | | |
| **2.6** | Mixed case lettering is used to enhance readability. *Exception*: full capitalization may be used for trade names (e.g., DILAUDID).[2] | | | | |
| **2.7** | TALLman lettering is used to differentiate look-alike, sound-alike drug names, where recommended.[2] **See FAQ 2.4** | | | | |
| **2.8** | Critical information (e.g., drug name, dose) is given prominence using contrasting type characteristics (e.g., bolding, colour).[2] | | | | |
| **2.9** | There is adequate white space between text characters and lines of text to enhance readability.[2,13] **See FAQ 2.6** | | | | |
| **2.10** | There is adequate contrast between type colour and label background to enhance readability.[2,14] **See FAQ 2.7** | | | | |
| **2.11** | There is adequate space for all data fields (including a bar code). This may require a text wrap option or continuation of text on an additional label.[2] | | | | |
| **2.12** | Logos and trade dress on product labels do not distract the user or impede the effective communication of key information to the user.[2] | | | | |
| **2.13** | Labels and inks used are durable enough to withstand normal handling (e.g., resistant to isopropyl or ethyl alcohol).[2] | | | | |

## 3. LABEL POSITION

| | | YES | PARTIAL | NO | N/A |
|---|---|---|---|---|---|
| **3.1** | The label position is standardized on the solution container to optimize text and bar code readability when the container is connected to the pump.[2,6] | | | | |
| **3.2** | Syringe labels are positioned so that they can be read from left to right when the syringe plunger is on the right side (i.e., labels are positioned so that the left edge of the label is proximal to the tip of the syringe). This allows users to "read up" when the syringe is inserted into the pump. **See FAQ 3.2** *Choose N/A if your organization does not compound epidural products in syringes.* | | | | |
| **3.3** | Syringe labels are positioned to ensure readability of syringe volume graduations.[15,16] **See FAQ 3.3** | | | | |

| | | | | | |
|---|---|---|---|---|---|
| **3.4** | Bag labels are placed on the same side with the name of the bag and/or base solution. The lot number and expiry date of the base solution are still visible, where possible.[15] **See FAQ 3.4** | | | | |
| **3.5** | Bag labels are oriented to ensure readability when the bag is hung for administration.[2] | | | | |
| **3.6** | Label placement on syringe or bag does not obscure visibility of contents (e.g., to check for precipitate).[6,16] | | | | |
| **3.7** | A duplicate label is applied to any outer packaging or over wrap that impairs visibility of the product container and label.[15] | | | | |

## 4. OTHER CONSIDERATIONS

| | | YES | PARTIAL | NO | N/A |
|---|---|---|---|---|---|
| **4.1** | Epidural products are administered using dedicated pumps and distinct tubing (e.g., yellow-coloured) that are clearly differentiated from other pumps and tubing in use in the care area.[17] *Choose N/A if your organization is a commercial compounder.* | | | | |
| **4.2** | Compounded products are ordered using predefined order sets approved by an interdisciplinary committee, where appropriate. *Choose N/A if your organization is a commercial compounder.* | | | | |
| **4.3** | Master formulas for compounded products include a sample label and auxiliary labels to be applied to the medication container. *Choose N/A if your organization is a commercial compounder.* | | | | |
| **4.4** | Information required by end users is provided in a consistent sequence and format to support "mapping" between order sets, automated dispensing cabinet display screens, medication administration records, infusion pump programming screens and libraries, and the medication label. *Choose N/A if your organization is a commercial compounder.* | | | | |
| **4.5** | User (e.g., nurse, physician) testing of the legibility and readability of injectable compounded product labels is conducted, ideally using a simulation process that replicates actual practice.[4] | | | | |
| **4.6** | Changes to pumps, pump libraries and labels are managed in a systematic manner using quality improvement principles, and only done by designated staff following institution policy or standards of practice. *Choose N/A if your organization is a commercial compounder.* | | | | |
| **4.7** | Label content and design is re-evaluated as needed (e.g., identified safety risk or whenever there is a change in infusion equipment). | | | | |

**LEGEND**

Items specific to epidural medication labels

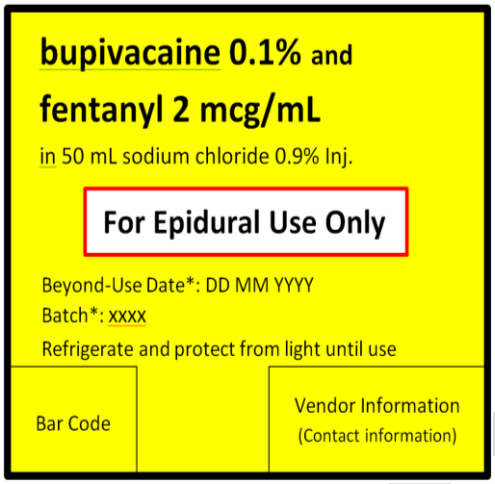
Items from the general checklist

## LABEL EXAMPLES

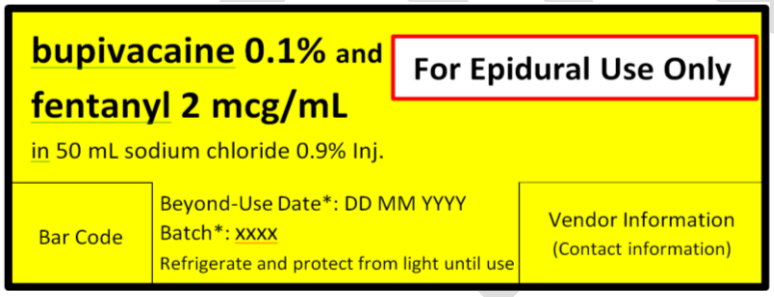
**These labels are provided as illustrative examples only and should not be considered for implementation without review of applicable labelling regulations/guidelines and user testing.**

For compounded products to be dispensed or administered to a specific patient, "another label must be added containing all information required by the respective provincial/territorial regulatory authority".[5]

### Bag




### Syringe




*__Commercial compounders__ will have:

- *Expiry Date* (instead of Beyond-Use Date)
- *Lot* (instead of Batch)
- *Overfill* (exact volume, where possible)

# Intravenous Opioids

**Why is a checklist for compounded intravenous opioid product labels needed?**

Compounded opioid medications are commonly administered by the intravenous route. Opioids are high-alert medications and, by definition, have a higher risk of patient harm if an error occurs. A review of medication errors, near miss incidents, and coroner cases reported to ISMP Canada identified opioids to be one of the more frequently reported causes of patient injury and death.[19]

The risk of unsafe use of compounded intravenous opioid products was considered significant to members of the Ontario Hospital Narcotic (Opioid) Collaborative Project, triggering recommendations to restrict admixing outside of pharmacy, and standardize infusion concentrations.[20,21]

Safe label content and design for compounded intravenous opioid products can help mitigate risk of errors and harm from these high-alert medications.

# Compounded Intravenous Opioid Label Checklist

| | |
|---|---|
| YES | This item is **fully implemented** for compounded intravenous opioid labels |
| PARTIAL | This item has been **partially implemented** for compounded intravenous opioid labels |
| NO | There has been **no activity** to implement this item for compounded intravenous opioid labels |
| N/A | Not applicable; selected items only |

## 1. LABEL CONTENT

| | | YES | PARTIAL | NO | N/A |
|---|---|---|---|---|---|
| 1.1 | The label does not contain error-prone abbreviations, symbols, or dose designations.[2,8] **See FAQ 1.1** | | | | |
| 1.2 | The label prominently identifies the route of administration using only affirmative statements (e.g., For Intravenous Use Only).[2,9] **See FAQ 1.2** | | | | |
| 1.3 | The label includes the total volume in the container (including overfill and additive volume *when required* for exact volume doses). | | | | |
| 1.4 | The strength is expressed in both total dose per total volume and dose per mL. The total dose per total volume is more prominent than, and in close proximity to, the dose per mL.[2] | | | | |
| 1.5 | Intravenous opioid products of higher than usual concentrations include additional warning label (e.g., HIGH CONCENTRATION).[22] | | | | |
| 1.6 | The base solution used to prepare the compounded product is noted on the label (e.g., "… in 50 mL sodium chloride 0.9%"). | | | | |
| 1.7 | The label includes the date beyond which the preparation cannot be used and must be discarded.[5,6] | | | | |
| 1.8 | The label includes storage requirements (e.g., Protect from light).[5,6] | | | | |
| 1.9 | An automated identifier (e.g., bar code) is provided in addition to the human-readable text.[2,10] | | | | |
| 1.10 | The label contains only the information needed to ensure safe use[5,11,12] and meet regulatory requirements. Non-essential information is minimized.[6,12] | | | | |
| 1.11 | The label includes appropriate warning statements. *Choose N/A if the compounded product does not require a warning.* | | | | |

## 2. LABEL DESIGN

| | | YES | PARTIAL | NO | N/A |
|---|---|---|---|---|---|
| **2.1** | Critical information (e.g., drug name, dose) appears first on the label and is positioned to distinguish it from non-critical information (e.g., vendor name). | | | | |
| **2.2** | A non-condensed, sans serif type style in the largest point size possible is used.[2] A minimum of 12 point is recommended for critical information. | | | | |
| **2.3** | Mixed case lettering is used to enhance readability. *Exception*: full capitalization may be used for trade names (e.g., DILAUDID).[2] | | | | |
| **2.4** | TALLman lettering is used to differentiate look-alike, sound-alike drug names, where recommended.[2] **See FAQ 2.4** | | | | |
| **2.5** | Critical information (e.g., drug name, dose) is given prominence using contrasting type characteristics (e.g., bolding, colour).[2] | | | | |
| **2.6** | There is adequate white space between text characters and lines of text to enhance readability.[2,13] **See FAQ 2.6** | | | | |
| **2.7** | There is adequate contrast between type colour and label background to enhance readability.[2,14] **See FAQ 2.7** | | | | |
| **2.8** | There is adequate space for all data fields (including a bar code). This may require a text wrap option or continuation of text on an additional label.[2] | | | | |
| **2.9** | Logos and trade dress on product labels do not distract the user or impede the effective communication of key information to the user.[2] | | | | |
| **2.10** | Labels and inks used are durable enough to withstand normal handling (e.g., resistant to isopropyl or ethyl alcohol).[2] | | | | |

## 3. LABEL POSITION

| | | YES | PARTIAL | NO | N/A |
|---|---|---|---|---|---|
| **3.1** | The label position is standardized on the solution container to optimize text and bar code readability when the container is connected to the pump.[2,16] | | | | |
| **3.2** | Syringe labels are positioned so that they can be read from left to right when the syringe plunger is on the right side (i.e., labels are positioned so that the left edge of the label is proximal to the tip of the syringe). This allows users to "read up" when the syringe is inserted into the pump. **See FAQ 3.2** | | | | |
| **3.3** | Syringe labels are positioned to ensure readability of syringe volume graduations.[15,16] **See FAQ 3.3** | | | | |
| **3.4** | Bag labels are placed on the same side with the name of the bag and/or base solution. The lot number and expiry date of the base solution are still visible, where possible.[15] **See FAQ 3.4** | | | | |
| **3.5** | Bag labels are oriented to ensure readability when the bag is hung for administration.[2] | | | | |
| **3.6** | Label placement on syringe or bag does not obscure visibility of contents (e.g., to check for precipitate).[6,16] | | | | |
| **3.7** | A duplicate label is applied to any outer packaging or over wrap that impairs visibility of the product container and label.[15] | | | | |

## 4. OTHER CONSIDERATIONS

| | | YES | PARTIAL | NO | N/A |
|---|---|---|---|---|---|
| 4.1 | Compounded products are ordered using predefined order sets approved by an interdisciplinary committee, where appropriate. *Choose N/A if your organization is a commercial compounder.* | | | | |
| 4.2 | Master formulas for compounded products include a sample label and auxiliary labels to be applied to the medication container. *Choose N/A if your organization is a commercial compounder.* | | | | |
| 4.3 | Information required by end users is provided in a consistent sequence and format to support "mapping" between order sets, automated dispensing cabinet display screens, medication administration records, infusion pump programming screens and libraries, and the medication label. *Choose N/A if your organization is a commercial compounder.* | | | | |
| 4.4 | User (e.g., nurse, physician) testing of the legibility and readability of injectable compounded product labels is conducted, ideally using a simulation process that replicates actual practice.[4] | | | | |
| 4.5 | Changes to pumps, pump libraries and labels are managed in a systematic manner using quality improvement principles, and only done by designated staff following institution policy or standards of practice. *Choose N/A if your organization is a commercial compounder.* | | | | |
| 4.6 | Label content and design is re-evaluated as needed (e.g., identified safety risk or whenever there is a change in infusion equipment). | | | | |

**LEGEND**

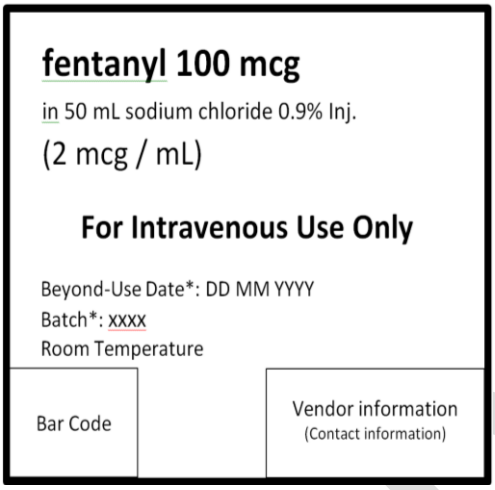
| | |
|---|---|
| | Items specific to intravenous opioid labels |
| | Items from the general checklist |

## LABEL EXAMPLES

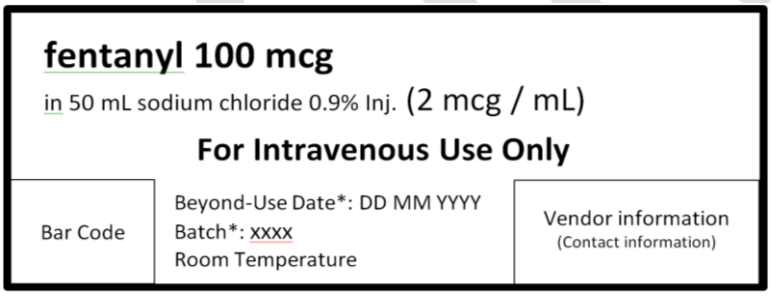
**These labels are provided as illustrative examples only and should not be considered for implementation without review of applicable labelling regulations/guidelines and user testing.**

For compounded products to be dispensed or administered to a specific patient, "another label must be added containing all information required by the respective provincial/territorial regulatory authority".[5]

### Bag




### Syringe




*__Commercial compounders__ will have:

- *Expiry Date* (instead of Beyond-Use Date)
- *Lot* (instead of Batch)
- *Overfill* (exact volume, where possible)

# FREQUENTLY ASKED QUESTIONS (FAQs)

**FAQ 1.1 Does ISMP Canada have a list of dangerous abbreviations, symbols and dose designations?**
ISMP Canada's Do Not Use List of Dangerous Abbreviations, Symbols and Dose Designations[23] is available from: https://www.ismp-canada.org/download/ISMPCanadaListOfDangerousAbbreviations.pdf

**FAQ 1.2 Why are alerts using words "NOT FOR" discouraged on injectable compounded product labels?**
Human factors studies have shown that alerts such as "NOT FOR INTRAVENOUS USE" could in fact be seen or registered as "FOR INTRAVENOUS USE". Affirmative statements are less prone to confusion.[2,9]

**[EPIDURAL] FAQ 1.3 Why do we propose expressing the dose of the anaesthetic agent in percentage, rather than in dose per mL or dose per total volume?**
Expressing the dose of the anaesthetic agent in percentage maintains consistency with manufacturer labels and packages which give prominence to this information. Additionally, this is aligned with stakeholder feedback that this is the most common practice for expressing dosage of anaesthetic agents and, as such, is familiar to clinicians.[17]

**FAQ 1.10 What are medication examples that require warning statements?**

- **vincristine**: "For Intravenous Use Only—Fatal if Given by Other Routes"[2,24]
- **neuromuscular-blocking agents**: "Warning: Paralyzing Agent" or "Paralyzing Agent"[2,25,26]
- **phenytoin**: "Warning: Cardiovascular Risk Associated with Rapid Infusion"[27]
- **3% sodium chloride**: "3% sodium chloride *CAUTION*"[28]

**FAQ 2.4 When should TALLman lettering be applied?**
TALLman lettering may be one strategy that can be considered when differentiation between confusable drug names is a concern. It should be used in accordance with identified confusable drug name pairs and published recommendations.[29,30,31] ISMP Canada's TALLman Lettering list is available from: https://www.ismp-canada.org/download/TALLman/TALLman_lettering.pdf

**FAQ 2.6 What is "adequate white space" on a label?**
White space should be used as liberally as possible to enhance the readability of compounded product labels. The Canadian Standards Association and the Canadian Society of Hospital Pharmacists suggest: one stroke width between characters (except **"L"** or "**I**"); one character space between two words; and one-half character height between lines of text.[2,13,14]

**FAQ 2.7 What is "adequate contrast" for type colour and label background?**
The contrast between the type colour and label background should be sufficient to maximize legibility of text on the label (e.g., apply dark type on a pale background, white type on black background for alerts).[13,32] The use of type and background colour combinations that are known to be very difficult to read should be avoided (e.g., black or yellow type on a red background).[2]

**FAQ 3.2 and 3.3 Why should labels be positioned in a specific location on a syringe?**
Syringe labels should be positioned in a standard location that ensures visibility of syringe volume graduations and optimizes readability when placed in the pump.

There are no defined Canadian standards for the direction of print on a prefilled syringe;[13] however, available standards for labelling of ampoules would suggest that syringe labels should be readable from left to right when the plunger is on the right side (i.e., "read up"). US standards state that for prefilled syringes, "the copy shall start flush with and read from the needle end".[33]

**FAQ 3.4 Why should the label be applied on the print side of a bag?**
If the label is applied to the blank side of a bag, and the bag is placed on a surface with the label side down, it could appear that the bag has not had any drug added to it.

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## ABOUT THE INSTITUTE FOR SAFE MEDICATION PRACTICES CANADA (ISMP CANADA)

The Institute for Safe Medication Practices Canada is an independent national not-for-profit organization committed to the advancement of medication safety in all healthcare settings. ISMP Canada works collaboratively with the healthcare community, regulatory agencies and policy makers, provincial, national and international patient safety organizations, the pharmaceutical industry and the public to promote safe medication practices.

ISMP Canada's mandate includes analyzing medication incidents, making recommendations for the prevention of harmful medication incidents, engaging in knowledge translation and facilitating quality improvement initiatives. Information about ISMP Canada's work with Canadians to prevent medication incidents is available at www.ismp-canada.org; and also www.safemedicationuse.ca a website designed for consumers.

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