

Pharmacists Prescribing Compounded Acetaminophen or Ibuprofen Suspension

Analgesic and antipyretic pediatric products (acetaminophen and ibuprofen) are in limited supply due to unprecedented demand. In Saskatchewan, a process has been developed to ensure safe and necessary access. Requirements may differ in other jurisdictions.

Per Health Canada Policy 51, pharmacists can support patients during drug shortages by compounding products; compounding can only be done pursuant to a prescription.¹ Health Canada has waived the requirement for a prescription for compounded analgesic/antipyretic pediatric medications until the shortage resolves. Health Canada recommends that a patient-healthcare professional relationship exists, including appropriate documentation.

In Saskatchewan, a provincial [collaborative practice agreement](#) (CPA) has been created for Saskatchewan pharmacists to prescribe compounded acetaminophen or ibuprofen suspension. Although a prescription is not required by Health Canada, the CPA ensures safe and necessary access and supports the documentation requirement for a patient-healthcare professional relationship. The CPA is in effect for the duration of the analgesic/antipyretic pediatric medication shortage.

Pharmacists who prescribe under the CPA do not need to provide compounding services but do need to direct parents/caregivers to a pharmacy that does.

This page contains the Pharmacist Assessment and Prescription records for Compounded Acetaminophen Suspension and Compounded Ibuprofen Suspension, which are used for documentation. You will also find important prescribing considerations.

Key Takeaways

When providing compounded acetaminophen or ibuprofen suspension, pharmacists have several functions: prescribing, compounding, and dispensing.

- **The use of commercially available products is preferred.** Consider pharmacologic and non-pharmacologic alternatives as appropriate, the use of different dosage forms, and repackaging bulk supplies when able.
- **Pharmacists can prescribe compounded acetaminophen or ibuprofen** for individuals with a current therapeutic need (mild to moderate pain and/or fever) and for whom the commercial formulations available are not suitable (i.e.: unable to swallow tablets, unable to attain dose with available products).
- **Patients/caregivers need to be informed of the significant differences between compounded and commercial products.** These differences may include (but are not limited to) access, stability, and storage.

- **Pharmacy professionals who compound must follow NAPRA Model Standards for Pharmacy Compounding.** An appropriate Risk Assessment and Master Formulation Record with beyond-use date (BUD) are needed to comply with NAPRA Model Standards for Pharmacy Compounding.

Prescribing

Use the [Pharmacist Assessment and Prescription – Compounded Acetaminophen Suspension Record](#) or [Pharmacist Assessment and Prescription – Compounded Ibuprofen Suspension Record](#) to document prescribing.

- **Precautions/Contraindications:**
 - **Acetaminophen²:**
 - **Severe hepatic impairment or severe active liver disease:**
 - For these patients, treatment with another option should be considered first.
 - **Ibuprofen^{3,4}:** (refer to [Musculoskeletal Strains and Sprains – Treatment](#) for more information)
 - **Age:** Other treatments are preferred for infants < 4 months old. Commercially available products are indicated for infants and children 4 months of age and older.
 - **Pregnancy:**
 - NSAIDs are **NOT** recommended in patients **trying to conceive**, during the **first trimester** and at **20 weeks or later of pregnancy**.
 - **Health Canada recommends avoiding NSAIDs during weeks 20 and beyond of pregnancy** (Health Canada [advisory issued Jun. 8, 2021](#)).
 - **Cardiovascular and/or cerebrovascular disease:** Treatment with NSAIDs must be undertaken with caution in patients with pre-existing cardiovascular disease (CVD) or cerebrovascular disease.
 - CVD includes:
 - myocardial infarction, angina, heart failure
 - peripheral artery disease (e.g., intermittent claudication)
 - atherosclerosis
 - Cerebrovascular disease includes:
 - stroke or transient ischemic attack
 - **For these patients, treatment options other than NSAIDs should be considered first.**
 - **Gastrointestinal Disease:** NSAIDs are **contraindicated** in patients with active gastric, duodenal, or peptic ulcers and inflammatory bowel disease.
 - **Renal impairment:**
 - If CrCl <30 mL/min: contraindicated
 - If CrCl <60mL/min: may use NSAIDs short-term, but caution is required
 - **Risk factors for renal complications include:**
 - dehydration
 - heart failure
 - hypertension
 - pre-existing renal disease
 - **Dehydration:** prefer treatment options other than NSAIDs until rehydration is achieved
 - **Asthma with previous reaction to an NSAID or ASA:** Patients with a history of asthma or allergic-type reactions after taking an NSAID should avoid all nonselective NSAIDs including ASA.
 - **Bleeding risk**
 - NSAIDs have anti-platelet effects, which can increase the risk of a bleed.
 - This is especially a concern for **patients on warfarin or other anticoagulants**.

- **Concomitant medications:** Pharmacists can identify drug interactions (e.g., ACE inhibitors)
 - **Use of multiple NSAIDs** concurrently should be **avoided**.
- **Reason for Use of Compounded Product:** Ensure unable to swallow tablets/attain dose with OTC dosage forms. Prescribe compounded product only if all commercially available options have been ruled out.
- **Use of Compounded Product Considerations:** Patients/caregivers need to be informed about the use of a compounded product including access, storage, and stability. Prescribers must be able to compound the product or direct the patient/caregiver on where to have the product compounded.
- **Indication:** Pain (mild to moderate) or fever
 - The goal of treatment is patient comfort.
 - **Ibuprofen:** An assessment fee cannot be billed when OTC strength ibuprofen is prescribed by a pharmacist (either as a Minor Ailment or under the Collaborative Prescribing Agreement) because it is not a listed benefit of the Saskatchewan Drug Plan. If OTC ibuprofen is being considered to treat a Minor Ailment (dysmenorrhea, headache, or musculoskeletal strains and sprains) and there is a need for compounded ibuprofen suspension, it is not necessary to complete both the Minor Ailment PAR and the Pharmacists Assessment and Prescription for Compounded Ibuprofen Suspension record - complete the compounding documentation only.
- **Dosing:** For patients weighing ≤ 43 kg or < 12 years old, calculate dose based on weight; for patients >43 kg and ≥ 12 years, use fixed dosing.^{2,3}
- **Quantity:** Limited to a 7-day supply based on typical illness duration and to avoid medications being kept past their BUD.
- **Treatment Duration (nonprescription):**
 - **Acetaminophen⁵ and Ibuprofen⁶:** 3 days for fever and 5 days for pain without seeing a physician.
- **Informed Consent Obtained:** Patients/caregivers have the right to be informed about the benefits and risks of any treatment or procedure offered to them and to make a voluntary decision about whether to undergo the treatment or procedure. Consent must be informed, specific, given voluntarily and documented. Pharmacists must obtain informed consent from the patient (or from the person authorized to provide informed consent on the patient's behalf) prior to prescribing.

Compounding and Dispensing

NAPRA Model Standards for Pharmacy Compounding compliance was required by SCPP as of August 31, 2022. As is true for all prescriptions, it is expected that a pharmacist will review the prescription for each preparation and use expertise to determine whether the compounded preparation is appropriate for the patient. In addition, the pharmacist and/or pharmacy technician who is designated as the compounding supervisor must determine whether the appropriate knowledge and resources to develop the formulation and/or the appropriate equipment and competency to compound the preparation are available.⁷

A Risk Assessment and Master Formulation Record with beyond-use dating (BUD) must be developed using critically appraised, evidence-based data. Publicly accessible formulation records from Medisca Network are available at: [Potential Shortage Support - MEDISCA Network](#)

- **Concentration of compounded product:** Some compounding formulations have concentrations differing from commercially available products which increases the risk of medication errors.
 - Take extra caution in calculating doses.
 - Make dosing instructions clear on the label.
 - Include: “Do not take more than XX mg in 24 hours”.
- **Compound preparation practice reminders:** Use child safe lids and appropriate auxiliary labels (e.g., shake well, storage conditions).

Counselling

- Highlight the maximum daily dose and the dosing interval.
- Remind patients/caregivers that the compounded product - acetaminophen or ibuprofen - should not be combined with other products containing the same ingredient.
- Communicate appropriate storage conditions.
- Emphasize Beyond-use Date.
- Provide accurate measuring devices.

Resources for the General Public

[Caring for Kids](#): this website has pages dedicated to providing caregivers with information about common conditions and how to manage them. This is useful for providing non-medication alternatives.

- [Fever and temperature taking](#)
- [Using over-the-counter drugs to treat cold symptoms](#)
- [Colds in children](#)
- [Influenza in children](#)

[Alberta Health Services Health Education and Learning](#): this website covers symptoms and treatment of conditions including fever, common cold, influenza, and ear pain. The website also provides printable handouts. The information is available in 4 languages.

[Oak Valley Health](#) provides handouts to help parents and caregivers determine the appropriate dose using adult dosage forms if they are all that’s available.

- [Acetaminophen](#)
- [Ibuprofen](#)

References

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