

ISMP Canada Safety Bulletin

Volume 26 • Issue 1 • January 22, 2026

A Multi-Incident Analysis of Reports Associated with Prednisone or Prednisolone Therapy

- **A multi-incident analysis of 587 reports associated with prednisone or prednisolone identified 3 key themes:**
 - Complex tapering regimens
 - Unclear indications
 - Insufficient product differentiation (e.g., in electronic systems)
- **Key contributing factors:**
 - Missing clinical details
 - Challenges in workflow management
- **Key strategies:**
 - Clear documentation of indication, duration of treatment, and taper instructions
 - Independent double-checks (e.g., quantity calculations)
 - Avoidance of the “copy” function for prednisone or prednisolone prescriptions
 - Safeguards for look-alike/sound-alike products

Prednisone and prednisolone (the active form of prednisone) are widely used for both chronic inflammatory conditions and acute exacerbations. Due to their effects on multiple organ systems, prednisone and prednisolone carry a risk of serious adverse effects such as hypertension, hyperglycemia, and secondary adrenal insufficiency.^{1,2} This bulletin highlights the findings from an analysis of medication incidents associated with prednisone or prednisolone, with a focus on community pharmacy, and shares opportunities to prevent and/or mitigate associated risks.

METHODOLOGY

Medication incidents associated with prednisone or prednisolone, submitted in the 2-year period between June 2023 and May 2025, were extracted from ISMP Canada’s National Incident Data Repository for Community Pharmacies (NIDR), Consumer Reporting program, and Individual Practitioner Reporting database.* Search terms included the generic and brand names for prednisone and prednisolone, specifically “prednisone”, “Winpred”, “prednisolone”, and “Pediapred.” Reports were excluded if the incident description was absent or unclear. The multi-incident analysis was conducted according to the methodology outlined in the Canadian Incident Analysis Framework.³

* The databases are components of the Canadian Medication Incident Reporting and Prevention System (CMIRPS). More information about the databases is available from: <http://www.cmirps-scdpim.ca/?p=12>.

QUANTITATIVE FINDINGS

Of the 635 reports that were retrieved,[†] 587 (92.4%) were included in the analysis. Most of these incidents were reported as either near misses (52.8%) or causing no harm (39.5%) (Figure 1). The most common types of error were reported to be incorrect dose/frequency (n = 174) and incorrect quantity (n = 90) (Figure 2).

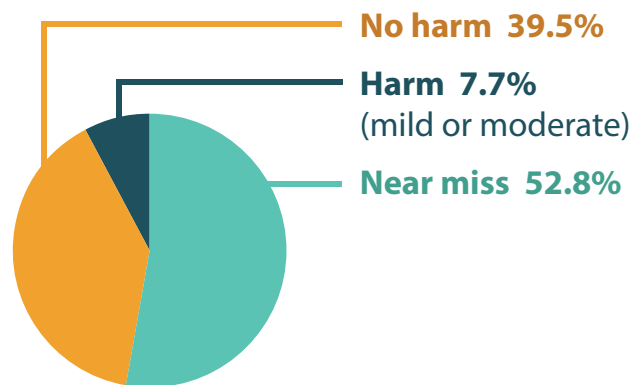


FIGURE 1. Levels of harm reported in incidents involving prednisone or prednisolone.

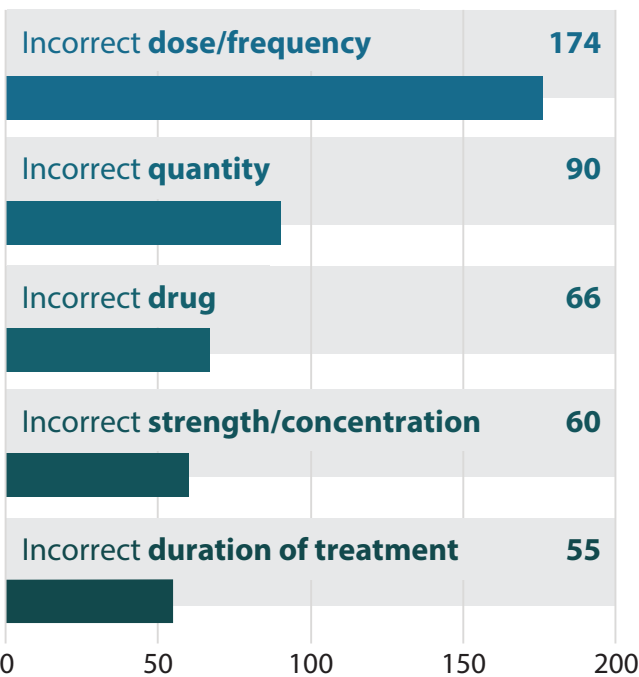


FIGURE 2. Top 5 types of error reported in incidents involving prednisone or prednisolone.

[†] It is recognized that it is not possible to infer or project the probability of incidents on the basis of voluntary reporting systems.

QUALITATIVE ANALYSIS

Three main themes and corresponding subthemes were identified from the qualitative analysis of reported incidents involving prednisone or prednisolone (Figure 3).

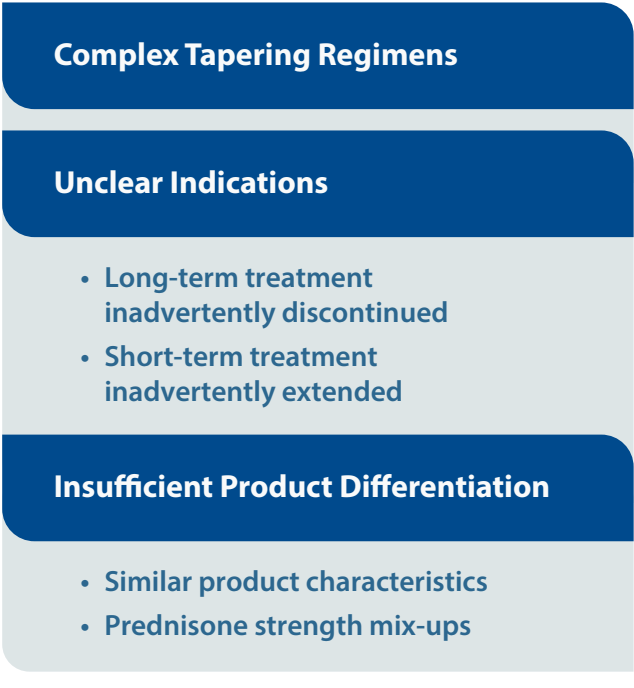


FIGURE 3. Themes and subthemes identified in the qualitative analysis of reported incidents involving prednisone or prednisolone.

THEME: Complex Tapering Regimens

Prednisone and prednisolone tapering regimens require multiple dose changes over a set period of time, and are specific for each patient (e.g., overall duration and the rate of dose reductions). Prescriptions for the taper can involve different doses, as well as multiple start and stop dates. Detailing each step of the taper often necessitates lengthy and complex instructions.

Contributing factors identified in this theme included the need to calculate and enter the quantity of medication to be dispensed, complexity and

variability of tapering regimens (e.g., use of multiple tablet strengths for a tapering regimen on a single prescription), and inadequate details included on prescriptions (e.g., missing start or stop dates or undocumented intentional changes to therapy).

Incident example: *A prescription for a prednisone taper indicated a daily dose reduction to 8 tablets for 3 days, then 6 tablets for 3 days, then 4 tablets for 3 days, then 3 tablets for 3 days, then 2 tablets for 3 days, then 1 tablet for 3 days, then stop. After taking the medication for several days, the patient alerted the pharmacy team that the quantity dispensed did not align with the intended tapering regimen. The directions on the vial label had erroneously described the initial dose reductions by 1 tablet (instead of 2 tablets) every 3 days.*

THEME: Unclear Indications

Subtheme: Long-term treatment inadvertently discontinued

Prednisone and prednisolone can be used to treat stable chronic conditions, with an increase in dose to address acute exacerbations. A key contributing factor in this subtheme was the use of the “copy” function to duplicate the patient’s previous (long-term) prednisone prescription as an entry for the new (short-term) prescription, resulting in replacement of the long-term prescription in the patient’s pharmacy profile. Another key contributing factor was unknown indication (i.e., acute or chronic medical condition).

Incident example: *A patient, who was using prednisone 10 mg daily long-term for arthritis, presented with a prescription for prednisone 50 mg for 5 days for acute exacerbation of another condition. The 10 mg prescription file was copied to create the new 50 mg prescription file, but doing so unintentionally removed the prednisone 10 mg daily prescription from the patient’s profile and blister pack medication list. The patient missed their daily 10 mg dose of prednisone for weeks and was admitted to hospital. The incident was discovered during the hospital’s medication reconciliation process.*

Subtheme: Short-term treatment inadvertently extended

Incidents within this subtheme involved the unintentional continuation of a patient’s short-term treatment with prednisone or prednisolone. In some instances, refills or extra doses prescribed to treat recurrent, unexpected acute episodes were inadvertently refilled for continuous use beyond the initial acute episode. Contributing factors included lack of indication on the prescription, unspecified treatment start and stop dates, and gaps in pharmacist follow-up/monitoring.

Incident example: *A patient was prescribed prednisone 50 mg for 5 days. The incorrect stop date was entered in the directions for use, which was overlooked during the independent double check. The patient received the medication for almost an additional month. The error was discovered during the billing check process.*

THEME: Insufficient Product Differentiation

Prednisone and prednisolone are not interchangeable. Prednisone is a prodrug that is converted by the liver into its active form, prednisolone.¹ While the pharmacodynamics (e.g., therapeutic effects) of these agents are similar, their pharmacokinetics (e.g., absorption, metabolism) differ.

Prednisone is available in tablet strengths of 1 mg, 5 mg, and 50 mg.¹ Prednisolone is available as an oral solution (1 mg/mL; often used for patients with impaired liver function and for pediatric patients), an ophthalmic solution (0.5% = 5 mg/mL), and an ophthalmic suspension (1% = 10 mg/mL).¹ Prednisolone is also available for veterinary use as a 5 mg tablet. The differences between these medications (and their various formulations and strengths), were often overlooked in the incidents reported in this theme.

Subtheme: Similar product characteristics

Selection errors involving confusion between prednisone and prednisolone may stem from their look-alike/sound-alike (LASA) drug names,⁴ their use

for similar indications, their overlapping strengths, or the erroneous belief that they are interchangeable (or identical). A few incidents described selection errors at order entry between prednisone 5 mg tablets (for human use) and prednisolone 5 mg tablets (for veterinary use). Contributing factors included confirmation bias and incomplete or missed clinical assessment.

Incident example: *The pharmacy received a pediatric prescription for prednisolone 5 mg oral tablets, with instructions to take 1 tablet twice daily for 5 days. Prednisone 50 mg oral tablets were inadvertently dispensed instead. At pick-up, the patient's mother expressed concern about the high dose and the child's inability to swallow tablets. The pharmacist contacted the prescriber for clarification and was told that prednisolone 1 mg/mL oral liquid was intended.*

Subtheme: Prednisone strength mix-ups

Similar-looking prednisone strengths can contribute to selection errors, especially if prescriptions are ambiguous and/or illegible.

Incident example: *Prednisone 5 mg tablets were dispensed for a patient instead of the intended 50 mg tablets. When the patient was about to take their medication, they noticed that the tablets were smaller than what they had previously received.*

RECOMMENDATIONS

Prescribers

- Document on the prescription and in the patient's health record
 - the indication⁵ for prednisone or prednisolone (e.g., long-term treatment, refills for recurrent exacerbations)
 - the precise duration of treatment (e.g., start and stop dates for short-term treatment)
 - stepwise tapering instructions with each step clearly documented (e.g., each step captured on a separate line, rather than in a dense paragraph)
 - intentional changes to the regimen (e.g., increased dose).

- Confirm that the patient/caregiver understands the indication for treatment, the planned duration of treatment, and the importance of tapering the medication before the medication is discontinued. Consider providing a printed copy of the taper instructions.

Pharmacy Teams

Clinical assessment

- Review prednisone and prednisolone prescriptions for clinical appropriateness, considering the indication, formulation, strength/concentration, dosing, and patient characteristics (e.g., pediatric weight).
- Conduct a best possible medication history (BPMH)⁶ during transitions of care to facilitate medication reconciliation and keep the patient's profile up to date.
 - For example, a patient may benefit from a medication reconciliation following hospitalization for exacerbation of an inflammatory condition.
 - Share the updated medication list with the patient/caregiver.
- Consider the use of compliance aids, such as personalized dosing calendars,⁷ detailed written instructions, and/or blister packaging, to support complicated tapering regimens.
 - Indicate the start and stop dates for each step of the taper, the tablet strength(s) for each step, and the number of tablets or doses to take each day until the tapering course is complete.⁸ For prednisolone liquid, the volume (mL) and dose (mg) are specified.

Order entry and dispensing

- Avoid use of the “copy” function during order entry for prednisone and prednisolone prescriptions, given the variety of possible indications and dosing regimens.
 - Inactivate previous prescriptions only if they refer to the same indication as the new one.
- Design workflow to support performing and verifying calculations without interruptions.
- Document quantity calculations and the independent double check, and keep the

- documentation with the original prescription.^{9,10}
- Consult the original prescription during the final check.
- Segregate storage of prednisolone and prednisone, including those intended for veterinary use (e.g., prednisolone 5 mg tablets). Consider using auxiliary labels for further product differentiation.
- Integrate bar-coding to mitigate selection errors between prednisone and prednisolone, as well as errors between different product strengths.¹¹

Patient/caregiver engagement

- During counselling, confirm with the patient/caregiver the name and dose of the medication they are expecting, the indication for the treatment, and the start and stop dates for therapy.
 - Show the tablets (for prednisone) or liquid product (for prednisolone) being dispensed.
 - Provide detailed written instructions to support a tapering regimen.
 - Use the teach-back method to verify that the patient/caregiver can identify the medication and understand the directions for use.¹² Ensure that the patient's understanding aligns with information from the prescriber.

Health care software administrators

- Incorporate alerts in electronic prescribing and pharmacy software for prednisone and prednisolone. For example:
 - Look-alike/sound-alike drug names
 - Pediatric dosing limits
 - Veterinary products

CONCLUSION

This analysis of reported incidents involving prednisone or prednisolone identified several opportunities to reduce the risk of error, including clear and well-documented communication among members of the care team and with the patient/caregiver. The recommendations offered here are intended to support health care teams in considering how this shared learning can inform continuous quality improvement initiatives.

ACKNOWLEDGEMENTS

ISMP Canada gratefully acknowledges the patients/caregivers, health care providers, pharmacies, hospitals, long-term care homes, and other health organizations who have reported medication incidents for analysis and shared learning. The expert review of this bulletin by the following individuals (in alphabetical order) and others from across the country is also recognized and appreciated:

Alberta College of Pharmacy; Anique Comeau BScPharm, Pharmacy Practice Assistant Manager, Nova Scotia Pharmacy Regulator, NS; Christopher Louizos BScPharm PharmD, Assistant Registrar, College of Pharmacists of Manitoba, MB; Jennifer LaPierre BScPharm, Deputy Registrar, Prince Edward Island College of Pharmacy, PEI; Sergio De Figueiredo RPhT, Senior Pharmacy Technician, Sunnybrook Health Sciences Centre, ON.

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The Canadian Medication Incident Reporting and Prevention System (CMIRPS) is a collaborative pan-Canadian program of Health Canada, the Canadian Institute for Health Information (CIHI), the Institute for Safe Medication Practices Canada (ISMP Canada) and Healthcare Excellence Canada (HEC). The goal of CMIRPS is to reduce and prevent harmful medication incidents in Canada.

Funding support provided by Health Canada. The views expressed herein do not necessarily represent the views of Health Canada.



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